

15-15143

IN THE
United States Court of Appeals
FOR THE NINTH CIRCUIT

RICHARD DENT; JEREMY NEWBERRY; ROY GREEN; J. D. HILL; KEITH VAN HORNE; RON STONE; RON PRITCHARD; JAMES MCMAHON; MARCELLUS WILEY; JONATHAN REX HADNOT, JR., On Behalf of Themselves and All Others Similarly Situated,

Plaintiffs-Appellants,

—v.—

NATIONAL FOOTBALL LEAGUE, a New York unincorporated association,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR NORTHERN CALIFORNIA, SAN FRANCISCO

BRIEF FOR PLAINTIFFS-APPELLANTS

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INTRODUCTION¹

For decades the National Football League (“NFL”) supplied controlled substances and prescription drugs to its players in amounts (*e.g.*, number of injections) and a manner (*e.g.*, without a prescription and failure to warn of side effects) that violate federal and state laws. It did so to make money – lots of money – while leaving players with latent injuries (*e.g.*, kidney failure that did not manifest until years after a player retired) and drug addictions they now battle on their own, without NFL assistance, years after their careers ended.

In early 2013, Plaintiffs first made the connection between their injuries and the aforementioned illegal conduct. In May 2014, on behalf of all retired players, they filed a complaint to seek redress for the injuries the class has suffered, and continues to suffer, as a result thereof. The NFL filed two motions to dismiss in response: one on preemption and the other for failure to state a claim. The District Court granted the preemption motion, finding the other moot. For the reasons discussed herein, the District Court committed reversible error in granting that motion as it misapplied the standard for deciding a motion to dismiss and failed to abide by Supreme Court and Ninth Circuit preemption decisions. This Court should thus reverse and remand this matter for further proceedings below.

¹ Because Plaintiffs are not corporate entities, they need not file a corporate disclosure statement.

JURISDICTIONAL STATEMENT

Plaintiffs appeal from the District Court's December 31, 2014 judgment granting the NFL's motion to dismiss. The District Court has jurisdiction under 28 U.S.C. § 1332(d)(2) because the proposed class consists of more than one hundred persons, the overall amount in controversy exceeds \$5,000,000 exclusive of interest, costs, and attorney's fees, and at least one plaintiff is a citizen of a state different from one defendant. Plaintiffs filed a timely notice of appeal on January 28, 2015. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

There are two issues on appeal:

1. In deciding a motion like that at issue here, a trial court must accept all well-pled allegations as true and cannot resolve disputed issues of fact. The District Court found the clubs, not the NFL as pled, were responsible for the conduct at issue and the NFL "should ... be given credit" for its actions. In substituting its view of the allegations for what Plaintiffs pled and resolving factual disputes in the NFL's favor, did the District Court commit reversible error?

2. Claims based on independent duties that require no contract interpretation avoid preemption. Plaintiffs based their claims on the NFL's failure to follow the law – an independent duty – and the contracts need not be consulted. In finding such claims preempted, did the District Court commit reversible error?

An addendum filed herewith includes all pertinent documents required.

STATEMENT OF THE CASE

On May 20, 2014, Hall of Famer Richard Dent and seven other retired football players filed a putative class action suit against the NFL. *See* ER 1389. The complaint was amended (“SAC”) to include two additional retired players as named Plaintiffs. ER 1390. Cumulatively, at least one of the ten Plaintiffs played in every NFL season from 1969 through 2012. ER 1294 – 1300. The gravamen of the SAC was simple: since 1971, the NFL obtained, maintained, and distributed to its players controlled substances and prescription drugs in violation of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.* (“Drug Control Act”); the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (“Food and Drug Act”), and corresponding state statutes.

Plaintiffs’ stories are remarkably similar. Regardless of the team or year, players were given large quantities of opioids, non-steroidal anti-inflammatory drugs, and anesthetics (collectively, “Medications”) without a prescription, with little regard for their medical history or potentially fatal interaction with other Medications, and without warning about possible side effects. ER 1292-93. While the types of Medications changed over the years, from amphetamines in the 1970s to Toradol in the 1990s and beyond, the volume and manner in which they were distributed remained constant. ER 1292.

The NFL engaged in this conduct to keep its players on the field and its revenues high, with the former becoming increasingly difficult over time and the latter becoming all-encompassing. From 1966 (when the AFL and NFL merged) to the present, the NFL has steadily expanded its schedule to include more games in an overall season and has also increased their frequency, with games now being played on Sundays, Mondays and Thursdays (and after college football ends, Saturdays too). ER 1289 – 90. The offseason is far shorter than it was 50 years ago, as now a player might participate in the Super Bowl in February and have to report back in April (and until recently, March), whereas they used to go months at a time with no involvement with their clubs. ER 1290.

In addition to more games and shorter off seasons, players have gotten bigger and stronger over the same period of time. Mel Kiper, one of ESPN's senior football analysts, noted that in 2011 offensive lineman were on average 24 percent heavier than those in 1979 and an average of 31 percent stronger than those in 1991. ER 1290. Whereas Art Donovan was a giant in the 1960s at 263 pounds, in recent years, the NFL has seen the likes of Aaron Gibson at 440 pounds and Albert Haynesworth at 350 pounds. *Id.*

Over the same time period, the NFL's revenue has skyrocketed. Between 1990 and 2013, that number jumped from \$1.5 billion to over \$9 billion. ER 1290. Commissioner Roger Goodell has set a target of \$27 billion by 2027. *Id.*

More games, longer seasons, shorter recovery between games, plus bigger and stronger players, equals more frequent and debilitating injuries. ER 1291. That is problematic for the NFL, which needs players on the field on any given Sunday – and Monday and Thursday – to keep revenue high. *Id.* Indeed, Plaintiffs Jeremy Newberry and Marcellus Wiley each spent an entire season in which they played every Sunday but never practiced because their injuries were too severe. *Id.* While one might think that injuries need not doom a player’s career, consider Ki-Jana Carter, the number one pick in the 1995 NFL Draft who tore knee ligaments in his first preseason game and never truly achieved his athletic (and thus earning) potential. *Id.*

In a survey by *The Washington Post*, nearly nine out of 10 former players reported playing while hurt. ER 1291. Fifty-six percent said they did this “frequently.” *Id.* An overwhelming number – 68 percent – said they did not feel like they had a choice whether to play hurt. *Id.* And they are right – the NFL gave them no choice. *Id.* Rather than allowing players the opportunity to rest and heal, the NFL illegally substituted Medications for proper health care. *Id.* For example, Plaintiff Keith Van Horne played an entire season on a broken leg and was not told about the break for five years. During that time, he received a constant diet of pills to deal with the pain. *Id.*

While discovery will sharpen the image, the similarity in which Medications were distributed to players on different clubs scattered across the country over five decades indicates that the decision to engage in this illegal conduct came from the NFL. This conclusion is supported by several facts pled to the District Court, including the following:

- NFL Executive Vice President Jeff Pash’s statements that painkiller abuse is “something that needs to be addressed on a broad basis, not just in the NFL, and it is something our doctors are looking at” (emphasis added), ER 1365;
- The NFL holds annual meetings to coordinate details regarding the distribution of Medications among all of its clubs, ER 35;
- The NFL mandated that its players sign a Toradol waiver, *Id.*;
- The NFL audits and reviews the distribution of Medications, *Id.*; and
- The imposition by the NFL of reporting software and bulk drug procurement from SportPharm, a company that voluntarily surrendered its pharmacy license in 2010 in the face of charges that it illegally distributed drugs to multiple NFL clubs, *Id.*

The foregoing allegations form the nucleus of the SAC, the operative pleading filed August 29, 2014 (and accepted on September 11). Plaintiffs further allege that, as a result of the NFL’s illegal conduct, they suffer from addiction, muscular-skeletal injuries, and harm to their internal organs. ER 1322-28. Plaintiffs brought state law claims for medical monitoring; fraud; fraudulent concealment; negligence *per se*; negligent misrepresentation, hiring and retention; and loss of consortium. ER 1352 – 73.

Though the Federal Rules of Civil Procedure do not allow it, the District Court permitted the NFL to file two motions to dismiss: one argued that § 301 of the Labor Management Relations Act (“LMRA”) preempted Plaintiffs’ claims while the other argued that Plaintiffs failed to state a claim. ER 464, 1259. Plaintiffs opposed both motions, ER 267, 301, and the NFL filed reply briefs, ER 231, 250.

On October 31, 2014, the District Court held oral argument on preemption only and requested supplemental briefing from a non-party, the National Football League Players Association, a union that represents only current and future NFL players (“NFLPA”). The District Court requested that the NFLPA analyze whether the claims at issue were or could have been grieved under any applicable collective bargaining agreement (“CBA”). ER 227-29. On November 19, the NFLPA responded that it did not think they could. ER 161-63. Two days later, the parties responded to the NFLPA brief after which the District Court requested² additional briefing from the NFLPA as to whether Plaintiffs could have grieved their claims at the time of the events in question or sued their doctors. ER 147, 154. The NFLPA responded on December 2 that, save for the possible exception of retired players covered by the 2011 CBA, they could not. ER 133. The parties thereafter responded to the December 2 NFLPA brief. ER 120, 127.

² The District Court also requested that the parties brief whether it could consult the CBAs and the parties agreed that it could. ER 146.

On December 17, 2014, the District Court entered an order granting the NFL's preemption motion. ER 2. "The main point" of that order "is that the [NFL] has addressed the[] serious concerns [of player health and safety] in a serious way – by imposing duties on the clubs via collective bargaining and placing a long line of health-and-safety duties on the team owners themselves.... That being so, plaintiffs' common law claims are preempted." ER 23.

The Order further provided that Plaintiffs could have until December 31 to file a motion for leave to amend their claims. ER 23. Plaintiffs did not, and the Court entered its final Order on December 31, 2014. ER 1.

SUMMARY OF THE ARGUMENT

The District Court analyzed Plaintiffs' complaint under a fundamental misperception: "the individual clubs mistreated their players and the league was negligent in failing to intervene and stop their alleged mistreatment." ER 7; *see also* ER 19 (describing Plaintiffs' legal theory as "the clubs violated the federal statutes (allegedly) and the league was negligent (allegedly) in failing to detect and right it") and ER 14 ("The nub of plaintiffs' claims is that the NFL is responsible for, and acts through, the clubs' medical staffs. As described above, Plaintiffs claim that the NFL owed a supervisory duty regarding the medical care of players."). The District Court's misunderstanding of the complaint infected every aspect of its analysis and eventual conclusion.

Plaintiffs have not alleged that they were mistreated by the individual clubs. Plaintiffs have not alleged that the clubs violated federal statutes. And Plaintiffs have not alleged that the NFL had only a “supervisory duty” regarding their medical care.

Rather, Plaintiffs claim that the NFL: (1) defrauded and concealed information from them about the Medications; (2) oversaw procurement of and monitored the dispensing of Medications for its clubs, and (3) violated duties established by detailed statutory schemes that regulate the distribution and administration of such Medications. Plaintiffs premise those claims on their right to have the health care they received be lawful; such claims are not dependent on whether the NFL or the clubs comported with contractual obligations to provide general health care. The question thus presented is: Given that Plaintiffs were provided medical care, was that care in violation of federal or state law and thus in breach of the rights bestowed by those laws on Plaintiffs?

In the appropriate analysis that should flow from that question, why Plaintiffs were provided healthcare is not relevant. But it is that question, not the question presented in the previous paragraph, the District Court sought to answer. In doing so, it followed a preemption rabbit hole it should never have gone down. The District Court’s decision should be reversed because it failed to recognize Plaintiffs’ claims as pled and did not correctly construe the duty at issue.

ARGUMENT

The District Court committed reversible error by (1) engaging in fact-finding and failing to credit Plaintiffs' well-pled allegations in contravention of well-established principles for deciding a motion to dismiss, and (2) misconstruing the duties and rights associated with Plaintiffs' claims in finding them preempted. In addition, the Court's conclusion regarding the grievance procedures available under the applicable CBAs is irrelevant.

I. The District Court's Order Exceeded the Scope of a Motion to Dismiss

A. Standard of Review

The NFL filed the motion at issue under Federal Rules of Civil Procedure 12(b)(1) and (6). *See* ER 142. This Court reviews *de novo* questions of law raised in dismissals under Rules 12(b)(1) and (6). *See Rhoades v. Avon Prods*, 504 F.3d 1151, 1156 (9th Cir. 2007). Where no evidentiary hearing has been held, "[t]his court must accept 'all allegations of material fact as true and construe them in the light most favorable'" to the plaintiff. *See North Cnty. Cmty. Alliance, Inc. v. Salazar*, 573 F.3d 738, 741 (9th Cir. 2009); *see also Pride v. Correa*, 719 F.3d 1130, 1133 (9th Cir. 2013) ("Whether we construe Defendants' motion as one under Rule 12(b)(6) or as a facial attack on subject matter jurisdiction under Rule 12(b)(1), all factual allegations in [the plaintiff's] complaint are taken as true and all reasonable inferences are drawn in his favor.").

In particular, the Court may not adopt a different construction of the plaintiff's allegations so as to require interpretation of a labor contract. *See, e.g., Galvez v. Kuhn*, 933 F.2d 773, 777 (9th Cir. 1991) (rejecting a trial court's characterization of the plaintiff's claims as "premised upon matters" in the labor contract and stating, "[c]amouflaged or not, [the plaintiff's] claim must be taken at face value at this early stage in the litigation.").

B. The District Court's Order Contains Impermissible Fact-Finding and Weighing of Evidence

The District Court began its legal analysis with this overarching premise: "[i]n evaluating any possible negligence by the NFL as alleged in the operative pleading, it would be necessary to take into account what the NFL has affirmatively done to address the problem, not just what it has not done." ER 8. The District Court then took stock of such affirmative actions and reached broad factual conclusions lacking any basis in the operative pleading's allegations, including:

- "The league has taken many steps to address the issue of player medical care by imposing on the clubs detailed provisions in numerous [CBAs] between the players' union and the NFL from 1968 onward." *Id.*
- "[T]his is not a situation in which the NFL has stood by and done nothing." *Id.* at 12.
- "The NFL should at least be given credit, in any negligence equation, for the positive steps it has taken[.]" *Id.* at 13.

- “It would be reasonable to place all responsibility at the club level, for that level is where the ... decisions are made, where the medical records are kept, and where players have daily contact with doctors.” *Id.* at 15.

Tellingly, the conclusion of the District Court’s order explained that “[t]he main point of this order is that the league has addressed these serious concerns in a serious way[.] ... These benefits may not have been perfect but they have been uniform across all clubs and not left to the vagaries of state law.” *Id.* at 23.

The District Court’s fact-based assumption that the NFL affirmatively acted “in a serious way” to address player medical care and should be “given credit” for those actions constituted bold circumvention of discovery, weighing of evidence, and resolution of factual disputes, all of which are inappropriate in deciding a motion like that at issue here. *See, e.g., Dahlia v. Rodriguez*, 735 F.3d 1060, 1076 (9th Cir. 2013). In any case, what healthcare the NFL contractually obligated itself to provide, if any, is a factually distinct matter from whether that healthcare was provided in an illegal manner and it is the latter issue, not the former, that the District Court should have addressed.

In sum, it was plainly inappropriate for the District Court to make factual determinations about the nature and extent of the NFL’s actions and opine as to whether it deserved credit for those actions while discarding the allegations Plaintiffs actually pled. For this reason alone, this Court should reverse. *See Dahlia*, 735 F.3d at 1076; *Rhoades*, 504 F.3d at 1156; *Pride*, 719 F.3d at 1133.

C. The District Court Mischaracterized the Complaint

Review on a motion to dismiss is limited to the contents of the complaint.³ *Diaz v. Int’l Longshoremen’s & Warehousemen’s Union, Local 13*, 474 F.3d 1202, 1205 (9th Cir. 2007). That means that here, the District Court could review only the SAC. It did not, or if it did, it chose to ignore the well-pled allegations contained therein and instead offered its own view of what transpired. Doing so was reversible error.

A cursory glance at the SAC reveals that Plaintiffs pled that the NFL, not the clubs, engaged in the conduct at issue. *See, e.g.*, ER 1289, ¶ 1 (“the NFL has intentionally, recklessly, and negligently created and maintained a culture of drug misuse”); *id.* ¶ 3 (“the NFL’s violations of Federal criminal laws”); ER 1293, ¶ 17 (“The NFL ... supplied players with ... opioids”); ER 1329, ¶ 192 (“Despite the NFL coordinating the illegal distribution of painkillers ... for decades”). Indeed, one need not look past the caption – Plaintiffs sued the NFL, not the clubs.

³ Of course, a trial court can also review documents attached to, or incorporated by, the complaint. *Van Buskirk v. CNN*, 284 F.3d 977, 980 (9th Cir. 2002). Here, the parties agreed that the Court could take judicial notice of the CBAs that the NFL attached to its motion to dismiss. ER 4. For the present analysis, this is of no moment. The SAC pled that the NFL, not the clubs, engaged in the conduct at issue and the CBAs, of course, do not evidence what the NFL (or for that matter, the clubs) did or did not do; rather, they evidence certain contractual obligations to which the parties thereto must abide. Even if the CBAs spoke directly to the issue (and they do not), they are merely evidence to be judged against Plaintiffs’ allegations and that is something a trial court cannot do on a motion like that at issue here.

The District Court, however, found that the “essence of plaintiffs’ claim for relief is that the individual clubs mistreated their players and the league was negligent in failing to intervene and stop their alleged mistreatment.” ER 7; *see also id.* at 14 (“[i]n sum, in deciding whether the NFL has been negligent in policing the clubs and in failing to address medical mistreatment by the clubs ...”); at 19 (“the clubs violated the federal statutes (allegedly) and the league was negligent (allegedly) in failing to detect and right it.”).

In doing so, the District Court committed reversible error. Plaintiffs plainly pled that the NFL, not the clubs, violated federal and state statutes and mistreated its players and in finding otherwise, the District Court impermissibly misconstrued Plaintiffs’ allegations. *Diaz*, 474 F.3d at 1205.

II. Plaintiffs’ Claims Are Not Preempted by § 301

This Circuit reviews *de novo* a decision to dismiss a complaint as preempted under § 301 of the LMRA. *See Harris v. Amgen, Inc.*, 788 F.3d 916, 934 (9th Cir. 2015) (reversing grant of motion to dismiss); *Humble v. Boeing Co.*, 305 F.3d 1004, 1008 (9th Cir. 2002) (reversing and remanding in part decision that claims were preempted under § 301 of the LMRA). Because Plaintiffs premise their claims on duties independent of any labor contract and which require no interpretation of such a contract, the District Court committed reversible error in finding those claims preempted.

A. Claims Derived from a Non-Negotiable, Statutory Duty Are Not Preempted

1. The Ninth Circuit Uses a Two-Part Preemption Test

Section 301 of the LMRA is a jurisdictional statute under which “[s]uits for violation of contracts between an employer and a labor organization representing employees ... may be brought in any district court of the United States having jurisdiction of the parties.” 29 U.S.C. § 185(a). The Supreme Court has expanded § 301’s scope beyond cases alleging contract violations to those whose resolution “is substantially dependent upon analysis of the terms of an agreement” or those where the claim “is inextricably intertwined with consideration of the terms of the labor contract.” *Allis-Chalmers v. Lueck*, 471 U.S. 202, 213, 220 (1985).

Under these standards, the Ninth Circuit has adopted a two-step inquiry for preemption. The court must first determine whether the asserted cause of action “involves a right conferred upon an employee by virtue of state law, not by a CBA.” *Burnside v. Kiewit Pac. Corp.*, 491 F.3d 1053, 1059 (9th Cir. 2007). If the right exists “solely as a result of the CBA,” the claim is preempted. *Id.* If, however, the right has a source other than a labor contract, the court then determines whether the right is nonetheless substantially dependent on an interpretation of the contract. *Id.* In essence, this test examines a state-law right to see whether its origin or substance lies in a labor contract.

The burden of proof rests on the party asserting a preemption defense. *Jimeno v. Mobil Oil Corp.*, 66 F.3d 1514, 1526 n.6 (9th Cir. 1995). The legal character of the plaintiff's claim controls the preemption analysis. *Livadas v. Bradshaw*, 512 U.S. 107, 123 (1994); *see also Humble*, 305 F.3d at 1008 (“As explained in *Cramer*, the plaintiff's claim is the touchstone for the preemption analysis, and ‘the need to interpret the CBA must inhere in the nature of the plaintiff's claim’ to trigger preemption”).

2. “*Interpretation*” is Construed Narrowly

The parties agree that Plaintiffs' claims do not involve rights that exist solely as a result of the CBA, *see, e.g.*, ER 257 – 65; thus, the sole inquiry is whether Plaintiffs' claims are substantially dependent on the CBAs. If liability can be established without interpreting a CBA, the claims are not “substantially dependent” or “inextricably intertwined” and thus not preempted. *See Burnside*, 491 F.3d at 1059 – 60. Even if terms of a CBA are “potentially relevant to the state law claims,” they are not preempted if there is no “guarantee that interpretation or direct reliance on the CBA terms will occur.” *Humble*, 305 F.3d at 1010. Given this requirement for actual interpretation or reliance, “the term ‘interpret’ is defined narrowly – it means something more than ‘consider,’ ‘refer,’ or ‘apply.’” *Balcorta v. Twentieth Century-Fox Film Corp.*, 208 F.3d 1102, 1108 (9th Cir. 2000).

“Interpret” does not “cover instances in which a [CBA] is merely consulted.” *Balcorta*, 208 F.3d at 1110 n.14; *Cramer v. Consol. Freightways, Inc.*, 255 F.3d 683, 691 (9th Cir. 2001) (“looking to” CBA does not require preemption); *Ward v. Circus Circus Casinos, Inc.*, 473 F.3d 994, 998 (9th Cir. 2007). Reference to the substantive right is insufficient for preemption as is “a hypothetical connection between the claim and the terms of the CBA[.]” *Cramer* at 691.

Because of this focus on the particulars of the plaintiff’s complaint, preemption is not warranted just because a defense or justification for conduct is based on a labor contract. *Humble*, 305 F.3d at 1011; *Caterpillar, Inc. v. Williams*, 482 U.S. 386, 398 (1987) (reliance on interpretation of a labor contract to establish a § 301 preemption defense “does not overcome the paramount policies embodied in the well-pleaded complaint rule”). Even if a labor contract “provides a remedy or duty related to a situation that is also directly regulated by non-negotiable state law,” the employee is not limited to a claim based on a collective-bargaining agreement. *Humble*, 305 F.3d at 1009.

Ultimately, and fundamentally, actions are not preempted when they rely on “nonnegotiable state-law rights ... independent of any right established by contract.” *Allis-Chalmers*, 471 U.S. at 213; *see also Livadas*, 512 U.S. at 123; *Cramer*, 255 F.3d at 683-84; *Burnside*, 491 F.3d at 1064.

3. *Claims Are Not Preempted If Based on Illegal Conduct or Duty Owed to All*

“Clearly, section 301 does not grant the parties to a collective-bargaining agreement the ability to contract for what is illegal under state law.” *Allis-Chalmers*, 471 U.S. at 212. Parties thus must abide by state and federal law and everyone has “a right to assume” they will do so. *Cramer*, 255 F.3d at 695. Even if a labor contract were to “expressly contemplate” illegal conduct by an employer, or purport to “reduce or limit” the expectation that the employer will abide by the law, any such provision would itself “be illegal and therefore unenforceable.” *Id.* at 695 – 96. Stated simply, “a CBA cannot validly sanction illegal action[.]” *Id.* at 697.

Where an employer is generally “accused of acting in a way that might violate the duty of reasonable care owed to every person in society,” negligence and other common-law claims have a sufficient non-contractual foundation to avoid preemption. *United Steelworkers v. Rawson*, 495 U.S. 362, 371 (1990); *see also Brown v. Nat’l Football League*, 219 F. Supp. 2d 372, 380 (S.D.N.Y. 2002); *see also Paige v. Henry J. Kaiser Co.*, 826 F.2d 857, 863 (9th Cir. 1987) (noting that simply because CBA provision incorporates existing laws does not, by itself, require contract interpretation) (overruled on other grounds in *Cal. Dep’t of Water Res. v. Powerex Corp.*, 533 F.3d 1087 (9th Cir. 2008)).

B. The Rights Asserted by Plaintiffs Are Not a Basis for Preemption

Plaintiffs claim that the NFL violated the Drug Control Act, Food and Drug Act, and corresponding state statutes with regard to the manner in which it (not the clubs) obtained and administered Medications. The corresponding right – to receive conforming medical care – exists by law, independent of any contract. The duty and right created by these statutes are non-negotiable and fully defined by the statutes themselves. Therefore, neither requires the interpretation of any CBA – both are circumscribed within the statutory provisions.⁴ A reviewing court need only compare/contrast the conduct at issue with the corresponding statutes to determine whether in fact the NFL violated the foregoing statutory regimes. As such, Plaintiffs’ claims are not preempted.

The District Court found otherwise because it concluded that: (1) statutory claims, to survive preemption, must derive from statutes that provide a private cause of action and (2) the CBAs covered the general subject matter of Plaintiffs’ claims – the provision of healthcare. But there is no basis for the District Court’s conclusion that a statute must authorize the claim; this Court has directly addressed the issue and found otherwise. And the Supreme Court and this Court have both

⁴ A non-negotiable statutory duty or right may be described in general terms (*e.g.*, “good faith”) or lack specific defined terms. In such instances, an interpretation of a CBA may be appropriate to define the term at issue. The statutes at issue here, however, provide for a highly-detailed regulatory scheme that expressly state obligations and define terms.

found that simply because the general subject matter of a claim is addressed in a CBA does not mean the claim is preempted.

1. Plaintiffs' Claims Do Not Require Interpretation of Collective-Bargaining Agreements

Plaintiffs premise their claims exclusively on the NFL's violation of federal and state statutory regimes governing Medications. The "substantive protection" afforded by such regimes exists "independent of the employer's obligations under its collective-bargaining agreement." *Cf. Atchison, Topeka & Santa Fe Rwy. v. Buell*, 480 U.S. 557, 565 (1987).

Plaintiffs could not have negotiated away, though the CBAs or otherwise, their right to receive such medical care in conformance with established law. As such, a court examining Plaintiffs' claims under the well-pleaded complaint rule would have no reason whatsoever to consider their labor contracts because the right at issue – to have the medical care provided in conformance with the law – is conferred by the law itself.

Yet the District Court, undertaking a vigorous review of the CBAs, found they would have to be interpreted because "the right to medical care established by the CBAs ... presumably included and still includes proper medical care in accordance with professional standards" and determined that it needed to analyze whether such medical care was in fact provided "in accordance with [such] standards." ER 12.

That statement rests on two premises: (1) Plaintiffs' right to have their medical care accord "with professional standards" is dependent on "the right to medical care established by the CBAs," and (2) the CBAs must be interpreted to determine whether Plaintiffs have a right to have their medical care accord with those professional standards. Neither is correct.

The right to have medical care provided in conformance with the law derives solely from the law itself, no matter what may be provided for in a CBA. *See Humble*, 305 F.3d at 1009. Put another way, even if a CBA confers such rights, it does not matter because the rights exist independent of the CBAs, which need not be interpreted. And if the CBAs had never existed, the players would nonetheless have had the right to receive conforming medical care. In short, because the right at issue exists independent of the CBAs, it need not be interpreted.⁵

Because labor contracts cannot modify non-negotiable rights created independently by law, whether a defendant has violated the law "is controlled only by the provisions of the ... statute." *Balcorta*, 208 F.3d at 1111. To avoid the foregoing principle, the District Court espoused a novel rule that statutory rights, even if non-negotiable, are nonetheless preempted unless brought under a direct statutory cause of action. In doing so, it committed reversible error.

⁵ Take, for example, a CBA that contains a provision that a team trainer, not licensed to practice medicine, may dispense controlled substances. Such a provision would conflict with federal law requiring that a licensed physician with a DEA number (or someone under their supervision) dispense drugs.

In support of its position, the District Court discussed two cases from this Court, *Cramer* and *Burnside*:

The plaintiffs [in *Cramer*] had brought a state statutory claim for invasion of privacy. So too in *Burnside* ... To be sure, the operative complaint here alleges violations of federal and state statutes – but only as an antecedent and predicate for follow-on state common law claims. No right of action is allowed or asserted under the statutes themselves.

ER 19. But neither *Cramer* nor *Burnside* state that enforcement of non-negotiable state-law rights must be authorized by statute to avoid preemption; in fact, though the District Court did not acknowledge it, the *Cramer* and *Burnside* plaintiffs asserted, like Plaintiffs here, common-law tort claims tethered to statutory rights.

The *Cramer* plaintiffs, alleging that their employer illegally placed recording equipment behind two-way mirrors in workplace bathrooms, brought state constitutional claims for invasion of privacy and a common-law tort claim for intentional infliction of emotion distress. They brought no claim directly authorized by statute and, to the extent they relied upon a statute, it did not provide a private cause of action and was utilized solely to provide context to their privacy claims.⁶ This Court held that, because plaintiffs sued on non-negotiable state-law rights independent of the CBAs, their constitutional and common-law claims were not preempted.

⁶ The District Court was incorrect when it stated “[t]he plaintiffs [in *Cramer*] brought a state statutory claim for invasion of privacy.” See ER 19.

So too in *Burnside*. Those plaintiffs brought two claims directly authorized by a state statute and a common-law conversion claim based on the same illegal conduct. This Court did not distinguish the common-law and statutory claims in holding that none were preempted by § 301 because the right upon which they were based “is a right conferred as a matter of state law that exists independent of the terms of the CBAs, and because the claims ... can be resolved without interpreting these agreements.” *Burnside*, 491 F.3d at 1074.

Other Supreme Court and Ninth Circuit cases confirm that common law claims derived from illegal conduct avoid preemption even if no statutory private right of action exists. For example, in *Galvez*, 933 F.2d at 777 – 780, this Court, considering common-law claims of assault and battery, referred to the criminal statutes for assault and battery – which do not provide for a private right of action – to support its conclusion that plaintiffs’ rights were “independent of any contract” and not preempted. *See also Lingle v. Norge Div. Magic Chef Inc.*, 486 U.S. 399, 410, 413 (1988). These cases definitively contravene the District Court’s conclusion that only causes of action directly authorized by statute may avoid preemption. Common law claims grounded in a non-negotiable statutory right independent of any labor contract are not properly preempted.

2. *Collective Bargaining About a General Subject Matter Does Not Preempt Related Claims*

This Court has held that claims are not preempted simply “because of the mere possibility that the[ir] subject matter ... was a proper subject of the collective bargaining process[.]” *Cramer*, 255 F.3d at 693; *see also* *Caterpillar*, 482 U.S. at 396 n.10. As such, a dispute about the interpretation of a CBA cannot be created by “picking out terms [from a contract] that refer” to the general subject matter of the claims at issue. *Cramer* at 694.

Reliance on “unwarranted assumptions” about terms of labor contracts, too, is an improper means of finding preemption. *Id.* at 693 n.6. This Court has “repeatedly frowned upon defendants who have invoked tangentially related CBA provisions in a strained and transparent effort to extinguish state-law claims via preemption.” *Burnside*, 491 F.3d at 1072.

The District Court, however, failed to adhere to this guidance:

The union and the league have bargained extensively over the subject of player medical care for decades. While these provisions do not specifically call out the prescribing of drugs and painkillers, they address more generally medical care, player health, and recovery time, and proper administration of drugs can reasonably be deemed to fall under these more general protections. Put differently, the right to medical care established by the CBAs, moreover, presumably included and still includes proper medical care in accordance with professional standards – including for the administration of drugs and painkillers....

ER 12.

The District Court reviewed the CBAs, “pick[ed] out terms that refer” to the general subjects of medical care and player health, and relied on pre-*Cramer* reasoning that, because the CBAs contain such provisions, all claims based on medical care are preempted. This analysis is legally obsolete and contrary to this Court’s and the Supreme Court’s precedent.

The CBAs at issue have no bearing on whether the NFL could illegally obtain and administer Medications. *Cf. Cramer*, 255 F.3d at 694 (provisions of CBA mentioning drug use and use of surveillance videotapes had no “bearing” on employer’s illegal spying). Similarly, references to these tangential provisions of the CBAs as a defense to this action are of no significance. *See id.* at 691 (“§ 301 preemption is not mandated simply because the defendant refers to the CBA in mounting a defense”). By relying on irrelevant provisions of the CBAs and making unwarranted assumptions about those provisions to preempt Plaintiffs’ claims, the District Court committed reversible error.

C. Out-of-Circuit Case-law Cited By the District Court Does Not Support Preemption of Plaintiffs’ Claims

Believing there to be no on-point precedent from this Court, the District Court reviewed out-of-circuit cases involving professional football players to determine how those courts evaluated § 301 preemption. ER 16. Those cases, however, establish only that the specific common-law claims being considered could not be resolved without interpretation of the CBAs. As such, they have no

bearing on Plaintiffs' claims. Equally important, certain claims in two of the cases (*Williams* and *Stringer*) were not preempted whereas certain claims in the other two cases (*Duerson* and *Smith*) were not addressed.

1. *Williams v. National Football League*

In *Williams v. Nat'l Football League*, 582 F.3d 863 (8th Cir. 2009), players sued the NFL after they were suspended for violating its written drug-testing policy. They brought statutory and common-law claims. The statutory claims were authorized by state laws on drug testing and use of "consumable products" outside the workplace.

Both statutes granted the players non-negotiable legal rights. Under the drug-testing statute, the employer could not bargain to provide less protection to its employees than the statute required; the employer's responsibilities under the consumable-products statute also could not "be waived or altered by the Union's agreement to the CBA." *Id.* at 880.

The Eighth Circuit confirmed that enforcement of those non-negotiable rights did not require interpreting the CBA; as to the claims brought under the drug-testing statute, the court held:

[A] court would have no need to consult the Policy in order to resolve the Players' DATWA claim. Rather, it would compare the facts and the procedure that the NFL actually followed with respect to its drug testing of the Players with DATWA's requirements for determining if the Players are entitled to prevail. Such a claim is not preempted.

Id. at 876.⁷

The District Court ignored this holding about the players’ statutory claims, focusing instead on the resolution of certain common-law claims, *see* ER 16, none of which were premised on statutory duties. Those claims – for breach of fiduciary duty, negligence, and gross negligence – were premised on general state common-law fiduciary relationships and tort concepts relating to voluntary assumption of tort liability. In the Eighth Circuit’s view, those rights and duties were not independent of the CBAs, and as such, were properly the subject of preemption.

The District Court treated this reasoning as favoring preemption of Plaintiffs’ negligence- and fraud-based claims in this case. With regard to the former, the District Court found such claims preempted pursuant to the Eighth Circuit’s holding that where an alleged duty “cannot be determined without examining the parties’ legal relationship and expectations as established by the CBA,” related claims are inextricable intertwined with consideration of the terms of the contract. ER 16 (citing *Williams*, 582 F.3d at 881). This analysis was misguided. The rights and duties asserted here are established by law and thus the parties’ legal relationship and expectations do not matter.

⁷ As for the consumable-products statute, the Eighth Circuit held that provisions of the CBA required “only mere consultation, which is insufficient to warrant preemption of an otherwise independent state law claim.” *Id.* at 877 (citing *Livadas*, 512 U.S. at 124-25).

As for the fraud claims, the District Court adopted the Eighth Circuit's holding that where plaintiffs "cannot demonstrate the requisite reasonable reliance to prevail on their claims without resorting to the CBA," they are preempted. ER

22. The District Court then applied this premise to two findings:

- "To resolve what duty the NFL owed to players in disclosing information about pain medication, interpretation of the CBAs would be required to determine the duty of care owed by individual clubs' physicians and trainers in disclosing information about pain medications." *Id.*
- "It would be necessary to interpret the CBA provisions on the disclosure of medical information to determine whether plaintiffs reasonably relied on the alleged lack of proper disclosure by the NFL." *Id.*

According to the District Court, the CBAs thus conceivably permitted the NFL to ignore its statutory obligation to provide mandatory disclosures about Medications. However, the duty at issue is established by law and the NFL must obey the law. *See Cramer*, 255 F.3d at 695. To resolve what duty was "owed to players in disclosing information about pain medication," no CBA interpretation is needed. The appropriate statutes are complete and self-contained in defining the duties they impose.

Moreover, according to the District Court, the CBAs would have to be consulted to determine whether Plaintiffs could have reasonably expected that the NFL would have followed the law. But everyone is required to abide by the law; "[i]ndeed, any contrary assumption would be irrational, because illegal behavior is unreasonable." *Cramer*, 255 F.3d at 695. Therefore, Plaintiffs had every right to

assume that the Medications would have been provided in a lawful manner. For both of Plaintiffs' negligence- and fraud-based claims, it makes no difference whether the CBAs mention the NFL's healthcare obligations; under the well-pleaded complaint rule, Plaintiffs' allegations that the NFL violated the duties at issue controls.

In sum, Plaintiffs' claims are more analogous to the non-preempted statutory claims in *Williams*. As with those claims, a reviewing court here need only "compare the facts and the procedure that the NFL actually followed" to the applicable legal requirements. 582 F.3d at 876. When properly read in its entirety, *Williams* militates against preemption in this case.

2. *Stringer v. National Football League and Duerson v. National Football League*

The District Court also considered the U.S. District Court for the Southern District of Ohio's decision in *Stringer v. Nat'l Football League*, 474 F. Supp. 2d 894 (S.D. Ohio. 2007), and the U.S. District Court for the Northern District of Illinois' decision in *Duerson v. Nat'l Football League*, No. 12C2513, 2012 WL 1658353 (N.D. Ill. May 11, 2012). In *Stringer*, the widow of an NFL player who died of heat stroke sued the NFL on allegations that it negligently published guidelines regarding heat safety. That negligence, she contended, caused athletic trainers, team physicians, and other staff members to misdiagnose and improperly treat her husband's symptoms.

Accepting that the NFL had an independent duty under state tort law to, if it voluntarily chose to publish heat stroke guidelines, do so non-negligently, the court weighed whether it could evaluate the potential breach thereof without interpreting a CBA. That analysis, in turn, was dependent on whether the NFL's conduct was reasonable. In the court's view, whether the NFL's conduct was reasonable depended on understanding what other duties might be owed plaintiff by his individual team as provided in the CBAs. Because the factfinder could not resolve plaintiff's claims without interpreting the CBAs, they were preempted.⁸

In *Duerson*, the estate of a deceased player sued the NFL on allegations that it had negligently failed to educate him about the risks of repeated head trauma, diagnose and treat brain damage he suffered as a result of head trauma, and implement policies that would have prevented him from continuing to play football after suffering head trauma. As in *Stringer*, the negligence claim required the factfinder to "evaluat[e] the reasonableness of the defendant's conduct." *Id.* at *3. Also as in *Stringer*, the court held that determining the reasonableness of the NFL's conduct would require interpreting a CBA to evaluate what other duties plaintiff was owed by his individual team.

⁸ The plaintiff in *Stringer* also brought a claim of negligence based on an asserted duty of the NFL to ensure that players had safe equipment. The court did not preempt that claim as "any such duty, if it exists, clearly has its source in common law" and the CBA, which was "largely silent on the topic of equipment safety," did not have to be interpreted. *Stringer*, 474 F. Supp. 2d at 912.

Stringer and *Duerson* both preempted state common-law claims on the ground that the labor contracts would have to be interpreted to adjudicate the reasonableness of the NFL's conduct. In using these cases to support its holding, the District Court failed to appreciate the difference between a tort claim employing a common-law reasonableness standard and a tort claim based on a statutory duty. Plaintiffs' claims do not require the court to weigh whether the NFL's actions were reasonable – what is “reasonable” is required by statute. This case does not involve the type of common-law analysis that made the tort claims in *Stringer* and *Duerson* “substantially dependent” on CBAs and those opinions do not support preemption of tort claims based on statutory duties.

3. *Smith v. National Football League Players' Association*

Lastly, the District Court reviewed *Smith v. The Nat'l Football League Players' Association*, No. 4:14CV01559, 2014 WL 6776306 (E.D. Mo. Dec. 2, 2014). In that case, former players who developed brain damage from repeated head trauma sued the NFLPA on a common-law tort claim of negligent misrepresentation, accusing it of not keeping them adequately informed about the risks of such head injuries. The claim of negligent misrepresentation required the plaintiffs to demonstrate that they justifiably relied on the alleged misrepresentations.

The U.S. District for the Eastern District of Missouri held that a factfinder could not resolve this question of justifiable reliance without knowing what information, pursuant to the CBA, the union was required to provide players. The negligent misrepresentation claim thus could not be resolved without CBA interpretation and was preempted.⁹ *Id.* In applying that holding here, the District Court failed to appreciate the difference between generally proving a negligent misrepresentation claim and doing so on the basis of a statute. The District Court also missed that both *Smith* and *Int'l B'hood of Elec. Workers v. Hechler*, 481 U.S. 851 (1987), addressed at ER 6, involved claims filed against a union. Both opinions stated that the source of the duty would be different in a lawsuit against an employer. *Smith* at *8; *Hechler* at 859 – 62.

Plaintiffs' misrepresentation claims do not require any interpretation of a labor contract to determine whether, *e.g.*, they would receive Medications in a manner mandated by federal and state law. Plaintiffs are entitled to expect lawful behavior from those with whom they interact. *See Cramer*, 255 F.3d at 695. Plaintiffs were therefore justified in expecting to receive Medications in a manner that conformed with applicable law.

⁹ Although the District Court asserted that “in assessing the ... union’s duties in relation to plaintiffs’ negligence and fraud claims, *Smith* found that ‘interpretation of the CBA is necessary[,]” ER 18, it did not. The *Smith* court considered plaintiff’s negligent misrepresentation claim only. Having found that claim preempted, which established federal jurisdiction, the court did not analyze the remaining claims. *Smith*, 2014 WL 6776306 at *7 n. 4.

Williams, *Stringer*, *Duerson*, and *Smith* confirm the undisputed reality that, in some jurisdictions, state-law claims based solely on common-law rights and duties are preempted because labor contracts may resolve questions about determinative legal relationships, modify common-law rights and duties, or define obligations among the parties that will establish whether objective common-law standards (such as whether conduct is “reasonable”) are met. These cases do not have persuasive force where, as here, non-negotiable statutory rights and duties replace elements of state common-law claims. The thorough and specified substance and content of those statutory duties obviate the need to understand anything about the terms for which the parties may have contracted. Finally, unlike *Williams* and *Stringer*, the District Court totally preempted all of Plaintiffs’ claims. That complete denial is not supported by those cases.

D. Other Lawsuits Related to Professional Football Establish That Plaintiffs’ Claims are Not Preempted

Though not addressed by the District Court, cases from other jurisdictions have rejected preemption of players’ claims similar to those claims here. Courts in those cases have permitted litigation to proceed even without the source of statutory law that Plaintiffs draw from here. *See generally Brown*, 219 F. Supp. 2d at 389. Mainly, however, these cases demonstrate that, when players assert non-negotiable duties that can be evaluated in light of state law rather than labor contracts, preemption is unwarranted.

In *Green v. Arizona Cardinals Football Club, LLC*, 21 F. Supp. 3d 1020 (E.D. Mo. 2014), a group of retired players brought negligence and fraud claims relating to misinformation they allegedly received about concussions and head trauma. The claims were premised upon non-negotiable state-law duties requiring an employer to provide a safe workplace and equipment; warn employees of dangers in the workplace; provide a sufficient number of competent co-workers; and promulgate and enforce safety rules. As here, the NFL contended that the claims were preempted pursuant to various provisions of CBAs that generally related to medical care. It further “hypothesize[d] that the CBAs could establish a contractually agreed upon standard of reasonableness less stringent than what would be applied in the absence of the contracts.” *Id.* at 1029.

Noting that “[m]ere reference to part of a CBA is insufficient for preemption,” *id.* at 1028, the court held that the rights and duties at issue arose out of the common law, “not out of any particular terms in the CBAs,” *id.*, and that interpretation of those terms was not “essential to plaintiffs’ case,” *id.* Because the rights and duties were non-negotiable, the claims could “be adjudged in accordance with standards” established by state law without need to consider whether a different standard was suggested by the labor contracts. *Id.* at 1029. The court further ruled that, even if common-law concepts of “reasonableness” or justifiable reliance did require interpretation of the CBAs, such interpretation

“would take the form of a defense” and could not be a basis for preemption. *Id.* at 1030. *Green* thus supports non-preemption here, where Plaintiffs assert non-negotiable duties that can be adjudged in accordance with the law rather than terms from a labor contract.

Non-negotiable rights and duties were also at issue in *Green v. Pro Football, Inc.*, 31 F. Supp. 3d 714 (D. Md. 2014) (“*Green II*”), in which the U.S. District Court for the District of Maryland considered claims relating to a team allegedly paying its players “bounties” for causing injuries. The court determined that paying such bounties would be illegal under state law and, even if the practice was negotiated in a labor contract, “[s]uch a contract is no more enforceable, even if lesser in degree, than a contract to kill[.]” *Id.* at 728-29. Claims based on non-negotiable state-law duties negated any need to consider, much less interpret, the substance of a collective-bargaining agreement and were not preempted.

III. The District Court’s Holding that Grievance Procedures Are Available to Plaintiffs is Irrelevant

“[W]hether a grievance arising from ‘precisely the same set of facts’” as the plaintiffs’ claims could be pursued is irrelevant in the preemption analysis. *Livadas*, 512 U.S. at 123; accord *Burnside*, 491 F.3d at 1060; see also *Green II*, 31 F. Supp. 3d at 728 (“Because the Court has already determined that none of [the plaintiff’s] claims arise from, or are inextricably intertwined with, the CBA, these grievance procedures quite simply do not apply to his state law claims.”).

This Court has allowed a plaintiff to proceed with state law claims even where she “could have decided to pursue a grievance” but “expressly eschewed” doing so. *Humble*, 305 F.3d 1010. Whether Plaintiffs could grieve their claims – which the CBAs do not seem to authorize – they have, instead, brought claims based on statutory duties and availed themselves of an appropriate forum to do so. The concurrent possibility of utilizing arbitration does not affect that choice.

The District Court ruled that “plaintiffs’ retiree status is not a bar to the grievance procedures.”¹⁰ ER 19. This decision ignored the NFLPA’s twice-stated position that it did “not believe that the specific claims asserted ... were or could have been grievable under any applicable [CBA].” *See* ER 161 – 63; *see also* ER 133. The District Court then described a broad ability of retired players to arbitrate grievances and supported this interpretation with two cases it misread.¹¹ The

¹⁰ The ability to grieve was a strong factor in the District Court’s analysis. It ordered, *sua sponte*, that the NFLPA submit a statement regarding Plaintiffs’ ability to grieve their claims. *See* ER 145. It further ordered, *sua sponte*, that the NFL identify specific provisions of the CBAs pursuant to which such grievances could have been brought and what the related remedies would be. *See* ER 131.

¹¹ Although the District Court thought *Matthews v. NFL Mgmt. Council* involved a player arbitrating against the NFL, the NFL Management Council brought the grievance against the player. The second case, *Givens v. Tennessee Football, Inc.*, merely stated that “because preempted claims must first be presented through the arbitration procedure established in a collective bargaining agreement, those claims should be dismissed.” 684 F. Supp. 2d 985, 991 (M.D. Tenn. 2010). The opinion undertook no analysis whether a retired player could arbitrate his grievance. Neither *Matthews* nor *Givens* supports the Court’s expansive understanding of a retired player’s ability to arbitrate grievances.

District Court then held that, based on the CBA provisions previously cited, the “types” of claims asserted by the plaintiff could be grieved “in important respects[.]” ER 20. Such a conclusion is not justified by the case law cited by the District Court or the opinion of the NFLPA that it solicited.

The existence of a grievance process, whether available to Plaintiffs or not, is irrelevant to the preemption analysis as repeatedly stated by this Court and the Supreme Court. The District Court committed reversible error by making the availability of a grievance an integral component in its preemption analysis.

CONCLUSION

For the foregoing reasons, Plaintiffs-Appellants respectfully request that this Court reverse the Order of the District Court finding the claims at issue preempted and remand this matter to the District Court for further proceedings consistent with this Court’s opinion.

Dated: October 9, 2015

SILVERMAN THOMPSON SLUTKIN &
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STATEMENT OF RELATED CASES

Plaintiffs are not aware of any related cases pending in the United States Court of Appeals for the Ninth Circuit.

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Dated: October 9, 2015

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CERTIFICATE OF SERVICE

I am employed in the City of Baltimore, State of Maryland. I am over the age of 18 and not a party to the within action; my business address is 201 N. Charles St., Suite 2600, Baltimore, MD 21201 and my email address is nwilson@mdattorney.com.

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Executed on October 9, 2015 at Baltimore, Maryland.

/s
Nicole Wilson

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§ 185. Suits by and against labor organizations, 29 USCA § 185

United States Code Annotated

Title 29. Labor

Chapter 7. Labor-Management Relations (Refs & Annos)

Subchapter IV. Liabilities of and Restrictions on Labor and Management

29 U.S.C.A. § 185**§ 185. Suits by and against labor organizations**

Currentness

(a) Venue, amount, and citizenship

Suits for violation of contracts between an employer and a labor organization representing employees in an industry affecting commerce as defined in this chapter, or between any such labor organizations, may be brought in any district court of the United States having jurisdiction of the parties, without respect to the amount in controversy or without regard to the citizenship of the parties.

(b) Responsibility for acts of agent; entity for purposes of suit; enforcement of money judgments

Any labor organization which represents employees in an industry affecting commerce as defined in this chapter and any employer whose activities affect commerce as defined in this chapter shall be bound by the acts of its agents. Any such labor organization may sue or be sued as an entity and in behalf of the employees whom it represents in the courts of the United States. Any money judgment against a labor organization in a district court of the United States shall be enforceable only against the organization as an entity and against its assets, and shall not be enforceable against any individual member or his assets.

(c) Jurisdiction

For the purposes of actions and proceedings by or against labor organizations in the district courts of the United States, district courts shall be deemed to have jurisdiction of a labor organization (1) in the district in which such organization maintains its principal office, or (2) in any district in which its duly authorized officers or agents are engaged in representing or acting for employee members.

(d) Service of process

The service of summons, subpoena, or other legal process of any court of the United States upon an officer or agent of a labor

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organization, in his capacity as such, shall constitute service upon the labor organization.

(e) Determination of question of agency

For the purposes of this section, in determining whether any person is acting as an “agent” of another person so as to make such other person responsible for his acts, the question of whether the specific acts performed were actually authorized or subsequently ratified shall not be controlling.

CREDIT(S)

(June 23, 1947, c. 120, Title III, § 301, 61 Stat. 156.)

29 U.S.C.A. § 185, 29 USCA § 185

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End of Document

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ADD3**§ 321. Definitions; generally, 21 USCA § 321**

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation[United States Code Annotated](#)[Title 21. Food and Drugs \(Refs & Annos\)](#)[Chapter 9. Federal Food, Drug, and Cosmetic Act \(Refs & Annos\)](#)[Subchapter II. Definitions \(Refs & Annos\)](#)**21 U.S.C.A. § 321****§ 321. Definitions; generally****Effective: June 22, 2009**[Currentness](#)

For the purposes of this chapter--

(a)(1) The term “State”, except as used in the last sentence of [section 372\(a\)](#) of this title, means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term “Territory” means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term “interstate commerce” means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term “Department” means Department of Health and Human Services.

(d) The term “Secretary” means the Secretary of Health and Human Services.

(e) The term “person” includes individual, partnership, corporation, and association.

(f) The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

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(g)(1) The term “drug” means (A) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to [sections 343\(r\)\(1\)\(B\)](#) and [343\(r\)\(3\)](#) of this title or [sections 343\(r\)\(1\)\(B\)](#) and [343\(r\)\(5\)\(D\)](#) of this title, is made in accordance with the requirements of [section 343\(r\)](#) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with [section 343\(r\)\(6\)](#) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term “counterfeit drug” means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) The term “device” (except when used in paragraph (n) of this section and in [sections 331\(i\)](#), [343\(f\)](#), [352\(c\)](#), and [362\(c\)](#) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(i) The term “cosmetic” means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

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(j) The term “official compendium” means the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, official National Formulary, or any supplement to any of them.

(k) The term “label” means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term “immediate container” does not include package liners.

(m) The term “labeling” means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term “new drug” means--

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a “new drug” if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of

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which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q)(1)(A) Except as provided in clause (B), the term “pesticide chemical” means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C.A. § 136 *et seq.*], including all active and inert ingredients of such pesticide. Notwithstanding any other provision of law, the term “pesticide” within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.

(B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):

(i) The definition in such clause for the term “pesticide chemical” does not include the substance if the substance is applied for such use on food, or the substance is included for such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is included for such use in water that comes into contact with the commodity, as follows:

(I) The substance is applied in the field.

(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

(ii) The definition in such clause for the term “pesticide chemical” does not include the substance if the substance is a food contact substance as defined in [section 348\(h\)\(6\)](#) of this title, and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on

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a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

With respect to the definition of the term “pesticide” that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act [[7 U.S.C.A. § 136 et seq.](#)], this clause does not exclude any substance from such definition.

(2) The term “pesticide chemical residue” means a residue in or on raw agricultural commodity or processed food of--

(A) a pesticide chemical; or

(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

(3) Notwithstanding subparagraphs (1) and (2), the Administrator may by regulation except a substance from the definition of “pesticide chemical” or “pesticide chemical residue” if--

(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this chapter other than [sections 342\(a\)\(2\)\(B\)](#) and [346a](#) of this title.

(r) The term “raw agricultural commodity” means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term “food additive” means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include--

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(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or

(2) a pesticide chemical; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act [21 U.S.C.A. § 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C.A. § 601 et seq.];

(5) a new animal drug; or

(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

(t)(1) The term “color additive” means a material which--

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term “color” includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant

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nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term “safe” as used in paragraph (s) of this section and in [sections 348, 360b, 360ccc, and 379e](#) of this title, has reference to the health of man or animal.

(v) The term “new animal drug” means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,--

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a “new animal drug” if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Provided that any drug intended for minor use or use in a minor species that is not the subject of a final regulation published by the Secretary through notice and comment rulemaking finding that the criteria of paragraphs (1) and (2) have not been met (or that the exception to the criterion in paragraph (1) has been met) is a new animal drug.

(w) The term “animal feed”, as used in paragraph (w)¹ of this section, in [section 360b](#) of this title, and in provisions of this chapter referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(x) The term “informal hearing” means a hearing which is not subject to [section 554, 556, or 557 of Title 5](#) and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

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(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(y) The term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(z) The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(aa) The term "abbreviated drug application" means an application submitted under [section 355\(j\)](#) of this title for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and--

(1) in the case of [section 335a](#) of this title, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of [sections 335b](#) and [335c](#) of this title, includes any supplement to such an application.

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(bb) The term “knowingly” or “knew” means that a person, with respect to information--

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(cc) For purposes of [section 335a](#) of this title, the term “high managerial agent”--

(1) means--

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for--

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product.

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(dd) For purposes of [sections 335a](#) and [335b](#) of this title, the term “drug product” means a drug subject to regulation under [section 355](#), [360b](#), or [382](#) of this title or under [section 262](#) of Title 42.

(ee) The term “Commissioner” means the Commissioner of Food and Drugs.

(ff) The term “dietary supplement”--

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that--

(A)(i) is intended for ingestion in a form described in [section 350\(c\)\(1\)\(B\)\(i\)](#) of this title; or

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(ii) complies with [section 350\(c\)\(1\)\(B\)\(ii\)](#) of this title;

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does--

(A) include an article that is approved as a new drug under [section 355](#) of this title or licensed as a biologic under [section 262 of Title 42](#) and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under [section 342\(f\)](#) of this title; and

(B) not include--

(i) an article that is approved as a new drug under [section 355](#) of this title, certified as an antibiotic under [section 357](#) of this title, or licensed as a biologic under [section 262 of Title 42](#), or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

Except for purposes of paragraph (g) and [section 350f](#) of this title, a dietary supplement shall be deemed to be a food within the meaning of this chapter.

(gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

(hh) The term "Administrator" means the Administrator of the United States Environmental Protection Agency.

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(ii) The term “compounded positron emission tomography drug”--

(1) means a drug that--

(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State’s law, for a patient or for research, teaching, or quality control; and

(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

(jj) The term “antibiotic drug” means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

(kk) The term “priority supplement” means a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (111 Stat. 2298).

(ll)(1) The term “single-use device” means a device that is intended for one use, or on a single patient during a single procedure.

(2)(A) The term “reprocessed”, with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.

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(B) A single-use device that meets the definition under clause (A) shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term “recycled” rather than the term “reprocessed”.

(3) The term “original device” means a new, unused single-use device.

(mm)(1) The term “critical reprocessed single-use device” means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

(2) The term “semi-critical reprocessed single-use device” means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(nn) The term “major species” means cattle, horses, swine, chickens, turkeys, dogs, and cats, except that the Secretary may add species to this definition by regulation.

(oo) The term “minor species” means animals other than humans that are not major species.

(pp) The term “minor use” means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

(qq) The term “major food allergen” means any of the following:

(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

(2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

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(B) A food ingredient that is exempt under [paragraph \(6\)](#) or [\(7\)](#) of [section 343\(w\)](#) of this title.

(rr)(1) The term “tobacco product” means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

(2) The term “tobacco product” does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in [section 353\(g\)](#) of this title.

(3) The products described in [paragraph \(2\)](#) shall be subject to subchapter V of this chapter.

(4) A tobacco product shall not be marketed in combination with any other article or product regulated under this chapter (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).

CREDIT(S)

(June 25, 1938, c. 675, § 201, 52 Stat. 1040; July 22, 1954, c. 559, § 1, 68 Stat. 511; Sept. 6, 1958, Pub.L. 85-929, § 2, 72 Stat. 1784; July 12, 1960, Pub.L. 86-618, Title I, § 101, 74 Stat. 397; Oct. 10, 1962, Pub.L. 87-781, Title I, § 102(a), Title III, § 307(a), 76 Stat. 781, 796; July 15, 1965, Pub.L. 89-74, §§ 3(a), 9(b), 79 Stat. 227, 234; July 13, 1968, Pub.L. 90-399, § 102, 82 Stat. 351; Oct. 24, 1968, Pub.L. 90-639, §§ 1, 4(a), 82 Stat. 1361, 1362; Oct. 27, 1970, Pub.L. 91-513, Title II, § 701(a), (g), 84 Stat. 1281, 1282; Oct. 21, 1972, Pub.L. 92-516, § 3(3), 86 Stat. 998; Apr. 22, 1976, [Pub.L. 94-278, Title V, § 502\(a\)\(2\)\(A\)](#), 90 Stat. 411; May 28, 1976, [Pub.L. 94-295](#), § 3(a)(1)(A), (2), 90 Stat. 575; Nov. 23, 1977, [Pub.L. 95-203](#), § 4(b)(3), 91 Stat. 1453; Sept. 26, 1980, [Pub.L. 96-359, § 3](#), 94 Stat. 1193; Nov. 16, 1988, [Pub.L. 100-670, Title I, § 107\(a\)\(1\)](#), 102 Stat. 3984; Nov. 8, 1990, [Pub.L. 101-535, § 5\(b\)](#), 104 Stat. 2362; Nov. 28, 1990, [Pub.L. 101-629, § 16\(b\)](#), 104 Stat. 4526; May 13, 1992, [Pub.L. 102-282, § 6](#), 106 Stat. 161; June 16, 1992, [Pub.L. 102-300](#), § 6(a), (b), 106 Stat. 240; Oct. 29, 1992, [Pub.L. 102-571, Title I, § 107\(1\)](#), 106 Stat. 4499; Aug. 13, 1993, [Pub.L. 103-80](#), §§ 3(b), (dd)(1), 4(b), 107 Stat. 775, 779; Oct. 25, 1994, [Pub.L. 103-417](#), §§ 3(a), (b), 10(a), 108 Stat. 4327, 4332; Aug. 3, 1996, [Pub.L. 104-170, Title IV, § 402](#), 110 Stat. 1513; Nov. 21, 1997, [Pub.L. 105-115, Title I, §§ 121\(a\)](#), 125(b)(2)(A), (e), 111 Stat. 2320, 2325, 2327; Oct. 30, 1998, [Pub.L. 105-324](#), § 2(a), (c), 112 Stat. 3035, 3037; Jan. 4, 2002, [Pub.L. 107-109](#), § 5(b)(1), 115 Stat. 1413; Oct. 26, 2002, [Pub.L. 107-250, Title III, § 302\(d\)](#), 116 Stat. 1619; Aug. 2, 2004, [Pub.L. 108-282, Title I, § 102\(b\)\(1\), \(5\)\(A\), \(B\), Title II, § 203\(c\)\(1\)](#), 118 Stat. 891, 902, 908; Sept. 27, 2007, [Pub.L. 110-85, Title X, § 1005\(c\)](#), 121 Stat. 968; June 22, 2009, [Pub.L. 111-31](#), Div. A, Title I, § 101(a), 123 Stat. 1783.)

Footnotes

1

So in original. Probably should be “paragraph (v)”.

21 U.S.C.A. § 321, 21 USCA § 321

Current through P.L. 114-49 approved 8-7-2015

ADD17

§ 321. Definitions; generally, 21 USCA § 321

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§ 331. Prohibited acts, 21 USCA § 331



KeyCite Yellow Flag - Negative Treatment

Unconstitutional or Preempted **Prior Version Limited on Constitutional Grounds by** [Commonwealth Brands, Inc. v. U.S.](#), W.D.Ky., Jan. 05, 2010

KeyCite Yellow Flag - Negative Treatment Proposed Legislation

United States Code Annotated**Title 21. Food and Drugs (Refs & Annos)****Chapter 9. Federal Food, Drug, and Cosmetic Act (Refs & Annos)****Subchapter III. Prohibited Acts and Penalties**

21 U.S.C.A. § 331

§ 331. Prohibited acts

Effective: November 27, 2013

[Currentness](#)

The following acts and the causing thereof are prohibited:

- (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.
- (b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.
- (c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
- (d) The introduction or delivery for introduction into interstate commerce of any article in violation of [section 344](#), [350d](#), [355](#), or [360bbb-3](#) of this title.
- (e) The refusal to permit access to or copying of any record as required by [section 350a](#), [350c](#), [350f\(j\)](#), [350e](#), [354](#), [360bbb-3](#), [373](#), [374\(a\)](#), [379aa](#), or [379aa-1](#) of this title; or the failure to establish or maintain any record, or make any report, required under [section 350a](#), [350c\(b\)](#), [350f](#), [350e](#), [354](#), [355\(i\)](#) or [\(k\)](#), [360b\(a\)\(4\)\(C\)](#), [360b\(j\)](#), [\(l\)](#) or [\(m\)](#), [360ccc-1\(i\)](#), [360e\(f\)](#), [360i](#), [360bbb-3](#), [379aa](#), [379aa-1](#), [387i](#), or [387t](#) of this title or the refusal to permit access to or verification or copying of any such required record; or the violation of any recordkeeping requirement under [section 2223](#) of this title (except when such violation is committed by a farm).

§ 331. Prohibited acts, 21 USCA § 331

(f) The refusal to permit entry or inspection as authorized by [section 374](#) of this title.

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in [section 333\(c\)\(2\)](#) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in [section 333\(c\)\(3\)](#) of this title, which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of [section 344](#) or [379e](#) of this title.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of [section 344](#), [348](#), [350a](#), [350c](#), [355](#), [360](#), [360b](#), [360c](#), [360d](#), [360e](#), [360f](#), [360h](#), [360i](#), [360j](#), [360ccc](#), [360ccc-1](#), [360ccc-2](#), [374](#), [379](#), [379e](#), [387d](#), [387e](#), [387f](#), [387g](#), [387h](#), [387i](#), or [387t\(b\)](#) of this title concerning any method or process which as a trade secret is entitled to protection; or the violating of [section 346a\(i\)\(2\)](#) of this title or any regulation issued under that section.¹ This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

§ 331. Prohibited acts, 21 USCA § 331

(l) Repealed. Pub.L. 105-115, Title IV, § 421, Nov. 21, 1997, 111 Stat. 2380.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of [subsections \(b\) or \(c\) of section 347](#) of this title.

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with [section 374](#) of this title.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

(p) The failure to register in accordance with [section 360](#) or [387e](#) of this title, the failure to provide any information required by [section 360\(j\)](#), [360\(k\)](#), [387e\(i\)](#), or [387e\(j\)](#) of this title, or the failure to provide a notice required by [section 360\(j\)\(2\)](#) or [387e\(i\)\(3\)](#) of this title.

(q)(1) The failure or refusal

(A) to comply with any requirement prescribed under [section 360h](#), [360j\(g\)](#), [387c\(b\)](#), [387g](#), [387h](#), or [387o](#) of this title;

(B) to furnish any notification or other material or information required by or under [section 360i](#), [360j\(g\)](#), [387d](#), [387i](#), or [387t](#) of this title; or

(C) to comply with a requirement under [section 360l](#) or [387m](#) of this title.

(2) With respect to any device or tobacco product, the submission of any report that is required by or under this chapter that is false or misleading in any material respect.

(r) The movement of a device or tobacco product in violation of an order under [section 334\(g\)](#) of this title or the removal

§ 331. Prohibited acts, 21 USCA § 331

or alteration of any mark or label required by the order to identify the device or tobacco product as detained.

(s) The failure to provide the notice required by [section 350a\(c\)](#) or [350a\(e\)](#) of this title, the failure to make the reports required by [section 350a\(f\)\(1\)\(B\)](#) of this title, the failure to retain the records required by [section 350a\(b\)\(4\)](#) of this title, or the failure to meet the requirements prescribed under [section 350a\(f\)\(3\)](#) of this title.

(t) The importation of a drug in violation of [section 381\(d\)\(1\)](#) of this title, the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of [section 353\(c\)](#) of this title, the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of [section 353\(c\)\(2\)](#) of this title, the distribution of a drug sample in violation of [section 353\(d\)](#) of this title or the failure to otherwise comply with the requirements of [section 353\(d\)](#) of this title, the distribution of drugs in violation of [section 353\(e\)](#) of this title, failure to comply with the requirements under [section 360eee-1](#) of this title, the failure to comply with the requirements under [section 360eee-3](#) of this title, as applicable, or the failure to otherwise comply with the requirements of [section 353\(e\)](#) of this title.

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under [section 360b\(a\)\(4\)\(A\)](#), [360b\(a\)\(4\)\(D\)](#), or [360b\(a\)\(5\)](#) of this title.

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under [section 350b](#) of this title.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under [section 381\(d\)\(3\)](#) of this title; the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with [section 381\(e\)](#) or [382](#) of this title, or with [section 262\(h\) of Title 42](#); or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under [section 360d\(c\)](#) of this title or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food--

(1) the submission of a report or recommendation by a person accredited under [section 360m](#) of this title that is false or misleading in any material respect;

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(2) the disclosure by a person accredited under [section 360m](#) of this title of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under [section 360m](#) of this title of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this chapter.

(z) Omitted

(aa) The importation of a prescription drug in violation of [section 384](#) of this title, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order under [section 334\(h\)](#) of this title, or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred under [section 335a\(b\)\(3\)](#) of this title.

(dd) The failure to register in accordance with [section 350d](#) of this title.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under [section 381\(m\)](#) of this title.

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under [section 381\(o\)](#) of this title.

(gg) The knowing failure to comply with [paragraph \(7\)\(E\) of section 374\(g\)](#) of this title; the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under [section 350e](#) of this title.

§ 331. Prohibited acts, 21 USCA § 331

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under [section 379aa](#) or [379aa-1](#) of this title) or the falsification of a serious adverse event report (as defined under [section 379aa](#) or [379aa-1](#) of this title) submitted to the Secretary.

(jj)(1) The failure to submit the certification required by [section 282\(j\)\(5\)\(B\) of Title 42](#), or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under [subsection \(j\) of section 282 of Title 42](#).

(3) The submission of clinical trial information under [subsection \(j\) of section 282 of Title 42](#) that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with [section 353c](#) of this title.

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under [section 355](#) of this title, a biological product licensed under [section 262 of Title 42](#), or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless--

(1) such drug or such biological product was marketed in food before any approval of the drug under [section 355](#) of this title, before licensure of the biological product under such [section 262 of Title 42](#), and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with--

(A) a regulation issued under [section 348](#) of this title prescribing conditions of safe use in food;

§ 331. Prohibited acts, 21 USCA § 331

(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D) a food contact substance notification that is effective under [section 348\(h\)](#) of this title; or

(E) such drug or biological product had been marketed for smoking cessation prior to September 27, 2007; or

(4) the drug is a new animal drug whose use is not unsafe under [section 360b](#) of this title.

(mm) The failure to submit a report or provide a notification required under [section 350f\(d\)](#) of this title.

(nn) The falsification of a report or notification required under [section 350f\(d\)](#) of this title.

(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under [section 333\(f\)](#) of this title.

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of [section 387k](#) of this title.

(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint,

§ 331. Prohibited acts, 21 USCA § 331

or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that

(1) the product is approved by the Food and Drug Administration;

(2) the Food and Drug Administration deems the product to be safe for use by consumers;

(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

(4) the product is safe or less harmful by virtue of--

(A) its regulation or inspection by the Food and Drug Administration; or

(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under [section 387c](#) of this title.

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the

§ 331. Prohibited acts, 21 USCA § 331

owner, operator, or agent in charge of such facility is not in compliance with [section 350g](#) of this title.

(vv) The failure to comply with the requirements under [section 350h](#) of this title.

(ww) The failure to comply with [section 350i](#) of this title.

(xx) The refusal or failure to follow an order under [section 350j](#) of this title.

(yy) The knowing and willful failure to comply with the notification requirement under [section 350f\(h\)](#) of this title.

(zz) The importation or offering for importation of a food if the importer (as defined in [section 384a](#) of this title) does not have in place a foreign supplier verification program in compliance with such [section 384a](#) of this title.

(aaa) The failure to register in accordance with [section 381\(s\)](#) of this title.

(bbb) The failure to notify the Secretary in violation of [section 360bbb-7](#) of this title.

(ccc)(1) The resale of a compounded drug that is labeled “not for resale” in accordance with [section 353b](#) of this title.

(2) With respect to a drug to be compounded pursuant to [section 353a](#) or [353b](#) of this title, the intentional falsification of a prescription, as applicable.

(3) The failure to report drugs or adverse events by an entity that is registered in accordance with [subsection \(b\) of section 353b](#) of this title.

CREDIT(S)

(June 25, 1938, c. 675, § 301, 52 Stat. 1042; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; Dec. 22, 1941, c. 613, § 1, 55 Stat. 851; July 6, 1945, c. 281, § 1, 59 Stat. 463; Mar. 10, 1947, c. 16, § 1, 61 Stat. 11; June 24, 1948, c. 613, § 1, 62 Stat. 582; Mar. 16, 1950, c. 61, § 3(b), 64 Stat. 20; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 7, 1953, c. 350, § 2, 67 Stat. 477; Sept. 6, 1958, Pub.L. 85-929, § 5, 72 Stat. 1788; July 12,

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1960, Pub.L. 86-618, Title I, §§ 104, 105(a), 74 Stat. 403; Oct. 10, 1962, Pub.L. 87-781, Title I, §§ 103(c), 104(e)(1), 106(c), 114(a), Title III, § 304, 76 Stat. 784, 785, 788, 791, 795; July 15, 1965, Pub.L. 89-74, §§ 5, 9(c), 79 Stat. 232, 235; July 13, 1968, Pub.L. 90-399, § 103, 82 Stat. 352; Oct. 24, 1968, Pub.L. 90-639, § 2(b), 82 Stat. 1361; Oct. 27, 1970, Pub.L. 91-513, Title II, § 701(a), 84 Stat. 1281; Aug. 16, 1972, Pub.L. 92-387, § 4(e), 86 Stat. 562; May 28, 1976, Pub.L. 94-295, §§ 3(b), 4(b)(1), 7(b), 90 Stat. 576, 580, 582; Sept. 26, 1980, Pub.L. 96-359, § 5, 94 Stat. 1193; Oct. 27, 1986, Pub.L. 99-570, Title IV, § 4014(b)(2), 100 Stat. 3207-120; Apr. 22, 1988, Pub.L. 100-293, § 7(a), 102 Stat. 99; Nov. 3, 1990, Pub.L. 101-502, § 5(j), 104 Stat. 1289; Nov. 5, 1990, Pub.L. 101-508, Title IV, § 4755(c)(2), 104 Stat. 1388-210; June 16, 1992, Pub.L. 102-300, § 3(a)(1), 106 Stat. 239; Oct. 29, 1992, Pub.L. 102-571, Title I, § 107(2), (3), 106 Stat. 4499; Aug. 13, 1993, Pub.L. 103-80, § 3(c), 107 Stat. 775; Oct. 22, 1994, Pub.L. 103-396, § 2(b)(1), 108 Stat. 4154; Oct. 25, 1994, Pub.L. 103-417, § 10(b), 108 Stat. 4332; Apr. 26, 1996, Pub.L. 104-134, Title II, § 2103, 110 Stat. 1321-319; Aug. 3, 1996, Pub.L. 104-170, Title IV, § 403, 110 Stat. 1514; Oct. 9, 1996, Pub.L. 104-250, § 5(d), 110 Stat. 3156; Nov. 21, 1997, Pub.L. 105-115, Title I, § 125(a)(2)(A), (C), (b)(2)(B), Title II, §§ 204(b), 210(c), Title IV, §§ 401(b), 421, 111 Stat. 2325, 2336, 2345, 2364, 2380; Oct. 28, 2000, Pub.L. 106-387, § 1(a) [Title VII, § 745(d)(1)], 114 Stat. 1549, 1549A-39; June 12, 2002, Pub.L. 107-188, Title III, §§ 303(b), 304(d), 305(b), 306(c), 307(b), 321(b)(2), 322(b), 116 Stat. 665, 666, 668, 670, 672, 676, 677; Oct. 26, 2002, Pub.L. 107-250, Title II, § 201(d), 116 Stat. 1609; Nov. 24, 2003, Pub.L. 108-136, Div. A, Title XVI, § 1603(c), 117 Stat. 1690; Dec. 8, 2003, Pub.L. 108-173, Title XI, § 1121(b)(1), 117 Stat. 2469; Apr. 1, 2004, Pub.L. 108-214, § 2(b)(2)(A), 118 Stat. 575; Aug. 2, 2004, Pub.L. 108-282, Title I, § 102(b)(5)(C), (D), 118 Stat. 902; Aug. 10, 2005, Pub.L. 109-59, Title VII, § 7202(d), (e), 119 Stat. 1913; Dec. 22, 2006, Pub.L. 109-462, §§ 2(c), 3(b), 4(a), 120 Stat. 3472, 3475; Sept. 27, 2007, Pub.L. 110-85, Title VIII, § 801(b)(1), Title IX, §§ 901(d)(1), 912(a), Title X, § 1005(d), 121 Stat. 920, 939, 951, 968; June 22, 2009, Pub.L. 111-31, Div. A, Title I, § 103(b), 123 Stat. 1833; Jan. 4, 2011, Pub.L. 111-353, Title I, §§ 102(d)(1), 103(e), 105(c), 106(d), Title II, §§ 204(j), 206(d), 211(b), (c), Title III, § 301(b), 124 Stat. 3889, 3898, 3904, 3906, 3937, 3943, 3953, 3954; Pub.L. 112-144, Title VII, §§ 714(a), 715(a), July 9, 2012, 126 Stat. 1073, 1075; Pub.L. 113-54, Title I, § 103(a), Title II, § 206(a), Nov. 27, 2013, 127 Stat. 597, 639.)

VALIDITY

<The United States Supreme Court has held section 301(f) of the Food, Drug, and Cosmetic Act, Act June 25, 1938, prohibiting a refusal to permit entry or inspection by federal officers, void for vagueness and to violate the Due Process Clause of the Fifth Amendment. *U.S. v. Cardiff*, U.S.Wash.1952, 73 S.Ct. 189, 344 U.S. 174, 97 L.Ed. 200.>

Footnotes

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So in original.

21 U.S.C.A. § 331, 21 USCA § 331

Current through P.L. 114-49 approved 8-7-2015

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§ 333. Penalties, 21 USCA § 333



KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated

Title 21. Food and Drugs (Refs & Annos)

Chapter 9. Federal Food, Drug, and Cosmetic Act (Refs & Annos)
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Subchapter III. Prohibited Acts and Penalties

21 U.S.C.A. § 333

§ 333. Penalties

Effective: January 1, 2015

Currentness

(a) Violation of [section 331](#) of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of [section 331](#) of this title shall be imprisoned for not more than one year or fined not more than \$1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section¹, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than \$10,000, or both.

(b) Prescription drug marketing violations

(1) Notwithstanding subsection (a) of this section, any person who violates [section 331\(t\)](#) of this title by--

(A) knowingly importing a drug in violation of [section 381\(d\)\(1\)](#) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of [section 353\(c\)\(1\)](#) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or

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knowingly counterfeiting such a coupon, in violation of [section 353\(c\)\(2\)](#) of this title, or

(D) knowingly distributing drugs in violation of [section 353\(e\)\(1\)](#) of this title,

shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated [section 331\(t\)](#) of this title because of a violation of [section 353\(c\)\(1\)](#) of this title or violated any State law prohibiting the sale, purchase, or trade of a drug sample subject to [section 353\(b\)](#) of this title or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than \$50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period.

(B) A civil penalty of not more than \$1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10-year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates [section 331\(t\)](#) of this title because of a failure to make a report required by [section 353\(d\)\(3\)\(E\)](#) of this title shall be subject to a civil penalty of not more than \$100,000.

(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of [section 331\(t\)](#) of this title because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug sample in violation of [section 353\(c\)\(1\)](#) of this title or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence--

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(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation,

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of [section 331\(t\)](#) of this title because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of [section 353\(c\)\(1\)](#) of this title, such person shall be entitled to one-half of the criminal fine imposed and collected for such violation but not more than \$125,000.

(6) Notwithstanding subsection (a) of this section, any person who is a manufacturer or importer of a prescription drug under [section 384\(b\)](#) of this title and knowingly fails to comply with a requirement of [section 384\(e\)](#) of this title that is applicable to such manufacturer or importer, respectively, shall be imprisoned for not more than 10 years or fined not more than \$250,000, or both.

(7) Notwithstanding subsection (a)(2), any person that knowingly and intentionally adulterates a drug such that the drug is adulterated under [subsection \(a\)\(1\), \(b\), \(c\), or \(d\) of section 351](#) of this title and has a reasonable probability of causing serious adverse health consequences or death to humans or animals shall be imprisoned for not more than 20 years or fined not more than \$1,000,000, or both.

(c) Exceptions in certain cases of good faith, etc.

No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated [section 331\(a\)](#) or [\(d\)](#) of this title, if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of [section 331\(a\)](#) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of [section 331\(d\)](#) of this title, that such article is not an article which may not, under the provisions of [section 344](#) or [355](#) of this title, be introduced into interstate commerce; or (3) for having violated [section 331\(a\)](#) of this title, where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this chapter, if such person establishes a guaranty or undertaking signed by, and

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containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this chapter; or (4) for having violated [section 331\(b\)](#), (c) or (k) of this title by failure to comply with [section 352\(f\)](#) of this title in respect to an article received in interstate commerce to which neither [section 353\(a\)](#) nor 353(b)(1) of this title is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated [section 331\(i\)\(2\)](#) of this title if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated [section 331\(i\)\(3\)](#) of this title if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

(d) Exceptions involving misbranded food

No person shall be subject to the penalties of subsection (a)(1) of this section for a violation of [section 331](#) of this title involving misbranded food if the violation exists solely because the food is misbranded under [section 343\(a\)\(2\)](#) of this title because of its advertising.

(e) Prohibited distribution of human growth hormone

(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under [section 355](#) of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by Title 18, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by Title 18, or both.

(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act [[21 U.S.C.A. § 801 et seq.](#)] for the purposes of forfeiture under section 413 of such Act [[21 U.S.C.A. § 853](#)].

(4) As used in this subsection the term “human growth hormone” means somatrem, somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

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(f) Violations related to devices

(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed \$15,000 for each such violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding. For purposes of the preceding sentence, a person accredited under [paragraph \(2\) of section 374\(g\)](#) of this title who is substantially not in compliance with the standards of accreditation under such section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of such section, shall be considered to have violated a requirement of this chapter that relates to devices.

(B) Subparagraph (A) shall not apply--

(i) to any person who violates the requirements of [section 360i\(a\)](#) or [360j\(f\)](#) of this title unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health,

(ii) to any person who commits minor violations of [section 360i\(e\)](#) or [360i\(g\)](#) of this title (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

(iii) to violations of [section 351\(a\)\(2\)\(A\)](#) of this title which involve one or more devices which are not defective.

(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of [section 342\(a\)\(2\)\(B\)](#) of this title or any person who does not comply with a recall order under [section 350l](#) of this title shall be subject to a civil money penalty of not more than \$50,000 in the case of an individual and \$250,000 in the case of any other person for such introduction or delivery, not to exceed \$500,000 for all such violations adjudicated in a single proceeding.

(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of [section 334](#) of this title or the injunction authorities of [section 332](#) of this title with respect to the article of food that is adulterated.

(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard

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to compelling testimony or production of documents as a presiding officer has under [section 346a\(g\)\(2\)\(B\)](#) of this title. The third sentence of paragraph (5)(A) shall not apply to any investigation under this paragraph.

(3)(A) Any person who violates [section 331\(jj\)](#) of this title shall be subject to a civil monetary penalty of not more than \$10,000 for all violations adjudicated in a single proceeding.

(B) If a violation of [section 331\(jj\)](#) of this title is not corrected within the 30-day period following notification under [section 282\(j\)\(5\)\(C\)\(ii\)](#) of Title 42, the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than \$10,000 for each day of the violation after such period until the violation is corrected.

(4)(A) Any responsible person (as such term is used in [section 355-1](#) of this title) that violates a requirement of [section 355\(o\)](#), [355\(p\)](#), or [355-1](#) of this title shall be subject to a civil monetary penalty of

(i) not more than \$250,000 per violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding; or

(ii) in the case of a violation that continues after the Secretary provides written notice to the responsible person, the responsible person shall be subject to a civil monetary penalty of \$250,000 for the first 30-day period (or any portion thereof) that the responsible person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed \$1,000,000 for any 30-day period, and not to exceed \$10,000,000 for all such violations adjudicated in a single proceeding.

(B) In determining the amount of a civil penalty under subparagraph (A)(ii), the Secretary shall take into consideration whether the responsible person is making efforts toward correcting the violation of the requirement of [section 355\(o\)](#), [355\(p\)](#), or [355-1](#) of this title for which the responsible person is subject to such civil penalty.

(5)(A) A civil penalty under paragraph (1), (2), (3), (4), or (9) shall be assessed, or a no-tobacco-sale order may be imposed, by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and [section 554](#) of Title 5. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty, or upon whom a no-tobacco-sale order is to be imposed, under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

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(B) In determining the amount of a civil penalty, or the period to be covered by a no-tobacco-sale order, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. A no-tobacco-sale order permanently prohibiting an individual retail outlet from selling tobacco products shall include provisions that allow the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1), (2), (3), (4), or (9). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(D) The Secretary may compromise, modify, or terminate, with or without conditions, any no-tobacco-sale order.

(6) Any person who requested, in accordance with paragraph (5)(A), a hearing respecting the assessment of a civil penalty or the imposition of a no-tobacco-sale order and who is aggrieved by an order assessing a civil penalty or the imposition of a no-tobacco-sale order may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued, or on which the no-tobacco-sale order was imposed, as the case may be.

(7) If any person fails to pay an assessment of a civil penalty--

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(8) If the Secretary finds that a person has committed repeated violations of restrictions promulgated under [section 387f\(d\)](#) of this title at a particular retail outlet then the Secretary may impose a no-tobacco-sale order on that person prohibiting the sale of tobacco products in that outlet. A no-tobacco-sale order may be imposed with a civil penalty under paragraph (1). Prior to the entry of a no-sale order under this paragraph, a person shall be entitled to a hearing pursuant to the procedures established through regulations of the Food and Drug Administration for assessing civil money penalties, including at a retailer's request

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a hearing by telephone, or at the nearest regional or field office of the Food and Drug Administration, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available.

(9) Civil monetary penalties for violation of tobacco product requirements

(A) In general

Subject to subparagraph (B), any person who violates a requirement of this chapter which relates to tobacco products shall be liable to the United States for a civil penalty in an amount not to exceed \$15,000 for each such violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding.

(B) Enhanced penalties

(i) Any person who intentionally violates a requirement of [section 387b\(5\)](#), [387b\(6\)](#), [387d](#), [387h\(c\)](#), or [387k\(a\)](#) of this title, shall be subject to a civil monetary penalty of--

(I) not to exceed \$250,000 per violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding; or

(II) in the case of a violation that continues after the Secretary provides written notice to such person, \$250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed \$1,000,000 for any 30-day period, and not to exceed \$10,000,000 for all such violations adjudicated in a single proceeding.

(ii) Any person who violates a requirement of [section 387k\(g\)\(2\)\(C\)\(ii\)](#) or [387k\(i\)\(1\)](#) of this title, shall be subject to a civil monetary penalty of--

(I) not to exceed \$250,000 per violation, and not to exceed \$1,000,000 for all such violations adjudicated in a single proceeding; or

(II) in the case of a violation that continues after the Secretary provides written notice to such person, \$250,000 for the first 30-day period (or any portion thereof) that the person continues to be in violation, and such amount shall double for every 30-day period thereafter that the violation continues, not to exceed \$1,000,000 for any 30-day period, and not to exceed \$10,000,000 for all such violations adjudicated in a single proceeding.

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(iii) In determining the amount of a civil penalty under clause (i)(II) or (ii)(II), the Secretary shall take into consideration whether the person is making efforts toward correcting the violation of the requirements of the section for which such person is subject to such civil penalty.

(g) Violations regarding direct-to-consumer advertising

(1) With respect to a person who is a holder of an approved application under [section 355](#) of this title for a drug subject to [section 353\(b\)](#) of this title or under [section 262 of Title 42](#), any such person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed \$250,000 for the first such violation in any 3-year period, and not to exceed \$500,000 for each subsequent violation in any 3-year period. No other civil monetary penalties in this chapter (including the civil penalty in subsection (f)(4)) shall apply to a violation regarding direct-to-consumer advertising. For purposes of this paragraph: (A) Repeated dissemination of the same or similar advertisement prior to the receipt of the written notice referred to in paragraph (2) for such advertisements shall be considered one violation. (B) On and after the date of the receipt of such a notice, all violations under this paragraph occurring in a single day shall be considered one violation. With respect to advertisements that appear in magazines or other publications that are published less frequently than daily, each issue date (whether weekly or monthly) shall be treated as a single day for the purpose of calculating the number of violations under this paragraph.

(2) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after providing written notice to the person to be assessed a civil penalty and an opportunity for a hearing in accordance with this paragraph and [section 554 of Title 5](#). If upon receipt of the written notice, the person to be assessed a civil penalty objects and requests a hearing, then in the course of any investigation related to such hearing, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation, including information pertaining to the factors described in paragraph (3).

(3) The Secretary, in determining the amount of the civil penalty under paragraph (1), shall take into account the nature, circumstances, extent, and gravity of the violation or violations, including the following factors:

(A) Whether the person submitted the advertisement or a similar advertisement for review under [section 379h-1](#) of this title.

(B) Whether the person submitted the advertisement for review if required under [section 353c](#) of this title.

(C) Whether, after submission of the advertisement as described in subparagraph (A) or (B), the person disseminated or caused another party to disseminate the advertisement before the end of the 45-day comment period.

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(D) Whether the person incorporated any comments made by the Secretary with regard to the advertisement into the advertisement prior to its dissemination.

(E) Whether the person ceased distribution of the advertisement upon receipt of the written notice referred to in paragraph (2) for such advertisement.

(F) Whether the person had the advertisement reviewed by qualified medical, regulatory, and legal reviewers prior to its dissemination.

(G) Whether the violations were material.

(H) Whether the person who created the advertisement or caused the advertisement to be created acted in good faith.

(I) Whether the person who created the advertisement or caused the advertisement to be created has been assessed a civil penalty under this provision within the previous 1-year period.

(J) The scope and extent of any voluntary, subsequent remedial action by the person.

(K) Such other matters, as justice may require.

(4)(A) Subject to subparagraph (B), no person shall be required to pay a civil penalty under paragraph (1) if the person submitted the advertisement to the Secretary and disseminated or caused another party to disseminate such advertisement after incorporating each comment received from the Secretary.

(B) The Secretary may retract or modify any prior comments the Secretary has provided to an advertisement submitted to the Secretary based on new information or changed circumstances, so long as the Secretary provides written notice to the person of the new views of the Secretary on the advertisement and provides a reasonable time for modification or correction of the advertisement prior to seeking any civil penalty under paragraph (1).

(5) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed

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under paragraph (1). The amount of such penalty, when finally determined, or the amount charged upon in compromise, may be deducted from any sums owed by the United States to the person charged.

(6) Any person who requested, in accordance with paragraph (2), a hearing with respect to the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty, may file a petition for de novo judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessments was issued.

(7) If any person fails to pay an assessment of a civil penalty under paragraph (1)--

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (6), or

(B) after a court in an action brought under paragraph (6) has entered a final judgment in favor of the Secretary,

the Attorney General of the United States shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (6) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

CREDIT(S)

(June 25, 1938, c. 675, § 303, 52 Stat. 1043; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; Oct. 26, 1951, c. 578, § 2, 65 Stat. 649; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; July 12, 1960, Pub.L. 86-618, Title I, § 105(b), 74 Stat. 403; July 15, 1965, Pub.L. 89-74, §§ 7, 9(d), 79 Stat. 233, 235; Oct. 24, 1968, Pub.L. 90-639, § 3, 82 Stat. 1361; Oct. 27, 1970, Pub.L. 91-513, Title II, § 701(b), 84 Stat. 1281; Apr. 22, 1976, Pub.L. 94-278, Title V, § 502(a)(2)(B), 90 Stat. 411; Apr. 22, 1988, Pub.L. 100-293, § 7(b), 102 Stat. 99; Nov. 18, 1988, Pub.L. 100-690, Title II, § 2403, 102 Stat. 4230; Nov. 28, 1990, Pub.L. 101-629, § 17(a), 104 Stat. 4526; Nov. 29, 1990, Pub.L. 101-647, Title XIX, § 1904, 104 Stat. 4853; Aug. 26, 1992, Pub.L. 102-353, § 3, 106 Stat. 941; Aug. 13, 1993, Pub.L. 103-80, § 3(e), 107 Stat. 775; Sept. 13, 1994, Pub.L. 103-322, Title XXXIII, § 330015, 108 Stat. 2146; Aug. 3, 1996, Pub.L. 104-170, Title IV, § 407, 110 Stat. 1535; Oct. 28, 2000, Pub.L. 106-387, § 1(a) [Title VII, § 745(d)(2)], 114 Stat. 1549, 1549A-40; Oct. 26, 2002, Pub.L. 107-250, Title II, § 201(c), 116 Stat. 1609; Dec. 8, 2003, Pub.L. 108-173, Title XI, § 1121(b)(2), 117 Stat. 2469; Sept. 27, 2007, Pub.L. 110-85, Title II, § 226(b), Title VIII, § 801(b)(2), Title IX, §§ 901(d)(4), 902(b)(1), (2), 121 Stat. 854, 920, 940, 943; June 22, 2009, Pub.L. 111-31, Div. A, Title I, § 103(c), 123 Stat. 1835; Jan. 4, 2011, Pub.L. 111-353, Title II, § 206(c), 124 Stat. 3943; Pub.L. 112-144, Title VII, § 716, July 9, 2012, 126 Stat. 1075; Pub.L. 113-54, Title II, § 207(a), Nov. 27, 2013, 127 Stat. 640.)

ADD39

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Footnotes

¹

So in original. Words “of this section” probably should not appear.

21 U.S.C.A. § 333, 21 USCA § 333

Current through P.L. 114-49 approved 8-7-2015

End of Document

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§ 352. Misbranded drugs and devices, 21 USCA § 352

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation[United States Code Annotated](#)[Title 21. Food and Drugs \(Refs & Annos\)](#)[Chapter 9. Federal Food, Drug, and Cosmetic Act \(Refs & Annos\)](#)[Subchapter V. Drugs and Devices](#)[Part A. Drugs and Devices \(Refs & Annos\)](#)**21 U.S.C.A. § 352****§ 352. Misbranded drugs and devices****Effective: November 27, 2013**[Currentness](#)

A drug or device shall be deemed to be misbranded--

(a) False or misleading label

If its labeling is false or misleading in any particular. Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under [section 355](#) of this title or under [section 262\(a\) of Title 42](#) for such drug and is based on competent and reliable scientific evidence. The requirements set forth in [section 355\(a\)](#) of this title or in [section 262\(a\) of Title 42](#) shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term “health care economic information” means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.

(b) Package form; contents of label

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) Prominence of information on label

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If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) Repealed. Pub.L. 105-115, Title I, § 126(b), Nov. 21, 1997, 111 Stat. 2327

(e) Designation of drugs or devices by established names

(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)--

(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

(ii) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, except that nothing in this subclause shall be deemed to require that any trade secret be divulged, and except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause shall not apply to nonprescription drugs not intended for human use.

(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of subclause (ii) or (iii) of clause (A) or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

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(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) As used in subparagraph (1), the term “established name”, with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to [section 358](#) of this title, or (B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient, except that where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homœopathic Pharmacopœia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homœopathic drug, in which case the official title used in the Homœopathic Pharmacopœia shall apply.

(4) As used in subparagraph (2), the term “established name” with respect to a device means (A) the applicable official name of the device designated pursuant to [section 358](#) of this title, (B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended for use by health care professionals or in blood establishments may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

(g) Representations as recognized drug; packing and labeling; inconsistent requirements for designation of drug

If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopœia and the Homœopathic Pharmacopœia of the United States, it shall be subject to the requirements of the United States Pharmacopœia with respect to packaging and labeling unless it is labeled and offered for sale as a homœopathic drug, in which case it shall be subject to the provisions of the Homœopathic Pharmacopœia of the United States, and not those of the United States Pharmacopœia, except that in the event of

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inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail.

(h) Deteriorative drugs; packing and labeling

If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) Drug; misleading container; imitation; offer for sale under another name

(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) Health-endangering when used as prescribed

If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(k) Repealed. [Pub.L. 105-115, Title I, § 125\(a\)\(2\)\(B\)](#), Nov. 21, 1997, 111 Stat. 2325

(l) Repealed. [Pub.L. 105-115, Title I, § 125\(b\)\(2\)\(D\)](#), Nov. 21, 1997, 111 Stat. 2325

(m) Color additives; packing and labeling

If it is a color additive the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under [section 379e](#) of this title.

(n) Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances

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In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in paragraph (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under paragraph (e) of this section, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with [section 371\(a\)](#) of this title, and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: “You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.”, except that (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of [sections 52 to 57 of Title 15](#). This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in [section 321\(m\)](#) of this title. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers. In the case of an advertisement for a drug subject to [section 353\(b\)\(1\)](#) of this title presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.

(o) Drugs or devices from nonregistered establishments

If it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under [section 360](#) of this title, if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under [section 381\(s\)](#) of this title, if it was not included in a list required by [section 360\(j\)](#) of this title, if a notice or other information respecting it was not provided as required by such section or [section 360\(k\)](#) of this title, or if it does not bear such symbols from the uniform system for identification of devices prescribed under [section 360\(e\)](#) of this title as the Secretary by regulation requires.

(p) Packaging or labeling of drugs in violation of regulations

If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to [section 1472](#) or [1473 of Title 15](#).

(q) Restricted devices using false or misleading advertising or used in violation of regulations

In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular, or (2) it is sold, distributed, or used in violation of regulations prescribed under [section 360j\(e\)](#) of this title.

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(r) Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter

In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing. Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of [sections 52 through 55 of Title 15](#). This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in [section 321\(m\)](#) of this title.

(s) Devices subject to performance standards not bearing requisite labeling

If it is a device subject to a performance standard established under [section 360d](#) of this title, unless it bears such labeling as may be prescribed in such performance standard.

(t) Devices for which there has been a failure or refusal to give required notification or to furnish required material or information

If it is a device and there was a failure or refusal (1) to comply with any requirement prescribed under [section 360h](#) of this title respecting the device, (2) to furnish any material or information required by or under [section 360i](#) of this title respecting the device, or (3) to comply with a requirement under [section 360j](#) of this title.

(u) Identification of manufacturer

(1) Subject to paragraph (2), if it is a reprocessed single-use device, unless it, or an attachment thereto, prominently and conspicuously bears the name of the manufacturer of the reprocessed device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer.

(2) If the original device or an attachment thereto does not prominently and conspicuously bear the name of the manufacturer of the original device, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying such manufacturer, a reprocessed device may satisfy the requirements of paragraph (1)

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through the use of a detachable label on the packaging that identifies the manufacturer and is intended to be affixed to the medical record of a patient.

(v) Reprocessed single-use devices

If it is a reprocessed single-use device, unless all labeling of the device prominently and conspicuously bears the statement “Reprocessed device for single use. Reprocessed by ____.” The name of the manufacturer of the reprocessed device shall be placed in the space identifying the person responsible for reprocessing.

(w) New animal drugs

If it is a new animal drug--

(1) that is conditionally approved under [section 360ccc](#) of this title and its labeling does not conform with the approved application or [section 360ccc\(f\)](#) of this title, or that is not conditionally approved under [section 360ccc](#) of this title and its label bears the statement set forth in [section 360ccc\(f\)\(1\)\(A\)](#) of this title; or

(2) that is indexed under [section 360ccc-1](#) of this title and its labeling does not conform with the index listing under [section 360ccc-1\(e\)](#) of this title or [360ccc-1\(h\)](#) of this title, or that has not been indexed under [section 360ccc-1](#) of this title and its label bears the statement set forth in [section 360ccc-1\(h\)](#) of this title.

(x) Nonprescription drugs

If it is a nonprescription drug (as defined in [section 379aa](#) of this title) that is marketed in the United States, unless the label of such drug includes a domestic address or domestic phone number through which the responsible person (as described in [section 379aa](#) of this title) may receive a report of a serious adverse event (as defined in [section 379aa](#) of this title) with such drug.

(y) Drugs subject to approved risk evaluation and mitigation strategy

If it is a drug subject to an approved risk evaluation and mitigation strategy pursuant to [section 355\(p\)](#) of this title and the responsible person (as such term is used in [section 355-1](#) of this title) fails to comply with a requirement of such strategy provided for under [subsection \(d\)](#), [\(e\)](#), or [\(f\)](#) of [section 355-1](#) of this title.

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(z) Postmarket studies and clinical trials; new safety information in labeling

If it is a drug, and the responsible person (as such term is used in [section 355\(o\)](#) of this title) is in violation of a requirement established under paragraph (3) (relating to postmarket studies and clinical trials) or paragraph (4) (relating to labeling) of [section 355\(o\)](#) of this title with respect to such drug.

(aa) Unpaid fees; failure to submit identifying information

If it is a drug, or an active pharmaceutical ingredient, and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by [section 379j-42\(a\)\(4\)](#) of this title or for which identifying information required by [section 379j-42\(f\)](#) of this title has not been submitted, or it contains an active pharmaceutical ingredient that was manufactured, prepared, propagated, compounded, or processed in such a facility.

(bb) If the advertising or promotion of a compounded drug is false or misleading in any particular.

(cc) If it is a drug and it fails to bear the product identifier as required by [section 360eee-1](#) of this title.

CREDIT(S)

(June 25, 1938, c. 675, § 502, 52 Stat. 1050; June 23, 1939, c. 242, § 3, 53 Stat. 854; 1940 Reorg. Plan No. IV, §§ 12, 13, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; Dec. 22, 1941, c. 613, § 2, 55 Stat. 851; July 6, 1945, c. 281, § 2, 59 Stat. 463; Mar. 10, 1947, c. 16, § 2, 61 Stat. 11; July 13, 1949, c. 305, § 1, 63 Stat. 409; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 5, 1953, c. 334, § 1, 67 Stat. 389; July 12, 1960, Pub.L. 86-618, Title I, § 102(b)(2), 74 Stat. 398; Oct. 10, 1962, Pub.L. 87-781, Title I, §§ 105(c), 112(a), (b), 131(a), Title III, § 305, 76 Stat. 785, 790, 791, 795; July 13, 1968, Pub.L. 90-399, § 105(a), 82 Stat. 352; Dec. 30, 1970, Pub.L. 91-601, § 7(d), 84 Stat. 1673; Dec. 30, 1970, Pub.L. 91-601, § 6(d), formerly § 7(d), 84 Stat. 1673; renumbered § 6(d), Aug. 13, 1981, [Pub.L. 97-35, Title XII, § 1205\(c\)](#), 95 Stat. 716; amended May 28, 1976, [Pub.L. 94-295](#), §§ 3(e), 4(b)(2), 5(a), 9(b)(2), 90 Stat. 577, 580, 583; Nov. 10, 1978, [Pub.L. 95-633, Title I, § 111](#), 92 Stat. 3773; June 16, 1992, [Pub.L. 102-300](#), § 3(a)(2), 106 Stat. 239; Oct. 29, 1992, [Pub.L. 102-571, Title I, § 107\(9\)](#), 106 Stat. 4499; Aug. 13, 1993, [Pub.L. 103-80, § 3\(m\)](#), 107 Stat. 777; Nov. 21, 1997, [Pub.L. 105-115, Title I, §§ 114\(a\), 125\(a\)\(2\)\(B\), \(b\)\(2\)\(D\), 126\(b\)](#), Title IV, § 412(c), 111 Stat. 2312, 2325, 2327, 2375; Oct. 26, 2002, [Pub.L. 107-250, Title II, § 206, Title III, §§ 301\(a\), 302\(a\)\(1\)](#), 116 Stat. 1613, 1616; Apr. 1, 2004, [Pub.L. 108-214, § 2\(b\)\(2\)\(B\), \(c\)\(1\)](#), 118 Stat. 575; Aug. 2, 2004, [Pub.L. 108-282, Title I, § 102\(b\)\(5\)\(E\)](#), 118 Stat. 902; Aug. 1, 2005, [Pub.L. 109-43, § 2\(c\)\(1\)](#), 119 Stat. 441; Dec. 22, 2006, [Pub.L. 109-462, § 2\(d\)](#), 120 Stat. 3472; Sept. 27, 2007, [Pub.L. 110-85, Title IX, §§ 901\(d\)\(3\)\(A\), \(6\)](#), 902(a), 906(a), 121 Stat. 940, 942, 943, 949; [Pub.L. 112-144, Title III, § 306, Title VII, §§ 702\(a\), 714\(c\)](#), July 9, 2012, 126 Stat. 1024, 1065, 1074; [Pub.L. 112-193, § 2\(a\)](#), Oct. 5, 2012, 126 Stat. 1443; [Pub.L. 113-54, Title I, § 103\(b\), Title II, § 206\(b\)](#), Nov. 27, 2013, 127 Stat. 597, 639.)

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§ 353. Exemptions and consideration for certain drugs, devices,..., 21 USCA § 353



KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated

Title 21. Food and Drugs (Refs & Annos)

Chapter 9. Federal Food, Drug, and Cosmetic Act (Refs & Annos)
--

Subchapter V. Drugs and Devices

Part A. Drugs and Devices (Refs & Annos)
--

21 U.S.C.A. § 353**§ 353. Exemptions and consideration for certain drugs, devices, and biological products****Effective: January 1, 2015**

Currentness

(a) Regulations for goods to be processed, labeled, or repacked elsewhere

The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(1) A drug intended for use by man which--

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under [section 355](#) of this title to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon

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an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of [section 352](#) of this title, except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to [section 355](#) of this title from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol “Rx only”.

(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in sections 4721, 6001, and 6151 of Title 26, or to marihuana as defined in section 4761 of Title 26.

(c) Sales restrictions

(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d) of this section, the term “drug sample” means a unit of a drug, subject to subsection (b) of this section, which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.

(2) No person may sell, purchase, or trade, offer to sell, purchase, or trade, or counterfeit any coupon. For purposes of this paragraph, the term “coupon” means a form which may be redeemed, at no cost or at a reduced cost, for a drug which is

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prescribed in accordance with subsection (b) of this section.

(3)(A) No person may sell, purchase, or trade, or offer to sell, purchase, or trade, any drug--

(i) which is subject to subsection (b) of this section, and

(ii)(I) which was purchased by a public or private hospital or other health care entity, or

(II) which was donated or supplied at a reduced price to a charitable organization described in [section 501\(c\)\(3\) of Title 26](#).

(B) Subparagraph (A) does not apply to--

(i) the purchase or other acquisition by a hospital or other health care entity which is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities which are members of such organization,

(ii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by an organization described in subparagraph (A)(ii)(II) to a nonprofit affiliate of the organization to the extent otherwise permitted by law,

(iii) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities which are under common control,

(iv) a sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, or

(v) a sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b) of this section.

For purposes of this paragraph, the term “entity” does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law and the term “emergency medical reasons” includes transfers of a drug between health care entities

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or from a health care entity to a retail pharmacy undertaken to alleviate temporary shortages of the drug arising from delays in or interruptions of regular distribution schedules.

(d) Distribution of drug samples

(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term “distribute” does not include the providing of a drug sample to a patient by a--

(A) practitioner licensed to prescribe such drug,

(B) health care professional acting at the direction and under the supervision of such a practitioner, or

(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).

(2)(A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) of this section may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. Such a distribution of drug samples may only be made--

(i) in response to a written request for drug samples made on a form which meets the requirements of subparagraph (B), and

(ii) under a system which requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and the return of the receipt to the manufacturer or authorized distributor of record.

(B) A written request for a drug sample required by subparagraph (A)(i) shall contain--

(i) the name, address, professional designation, and signature of the practitioner making the request,

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(ii) the identity of the drug sample requested and the quantity requested,

(iii) the name of the manufacturer of the drug sample requested, and

(iv) the date of the request.

(C) Each drug manufacturer or authorized distributor of record which makes distributions by mail or common carrier under this paragraph shall maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and shall maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to Federal and State officials engaged in the regulation of drugs and in the enforcement of laws applicable to drugs.

(3) The manufacturer or authorized distributor of record of a drug subject to subsection (b) of this section may, by means other than mail or common carrier, distribute drug samples only if the manufacturer or authorized distributor of record makes the distributions in accordance with subparagraph (A) and carries out the activities described in subparagraphs (B) through (F) as follows:

(A) Drug samples may only be distributed--

(i) to practitioners licensed to prescribe such drugs if they make a written request for the drug samples, or

(ii) at the written request of such a licensed practitioner, to pharmacies of hospitals or other health care entities.

A written request for drug samples shall be made on a form which contains the practitioner's name, address, and professional designation, the identity of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or authorized distributor of record of the drug sample, the date of the request and signature of the practitioner making the request.

(B) Drug manufacturers or authorized distributors of record shall store drug samples under conditions that will maintain their stability, integrity, and effectiveness and will assure that the drug samples will be free of contamination, deterioration, and adulteration.

(C) Drug manufacturers or authorized distributors of record shall conduct, at least annually, a complete and accurate

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inventory of all drug samples in the possession of representatives of the manufacturer or authorized distributor of record. Drug manufacturers or authorized distributors of record shall maintain lists of the names and address of each of their representatives who distribute drug samples and of the sites where drug samples are stored. Drug manufacturers or authorized distributors of record shall maintain records for at least 3 years of all drug samples distributed, destroyed, or returned to the manufacturer or authorized distributor of record, of all inventories maintained under this subparagraph, of all thefts or significant losses of drug samples, and of all requests made under subparagraph (A) for drug samples. Records and lists maintained under this subparagraph shall be made available by the drug manufacturer or authorized distributor of record to the Secretary upon request.

(D) Drug manufacturers or authorized distributors of record shall notify the Secretary of any significant loss of drug samples and any known theft of drug samples.

(E) Drug manufacturers or authorized distributors of record shall report to the Secretary any conviction of their representatives for violations of subsection (c)(1) of this section or a State law because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(F) Drug manufacturers or authorized distributors of record shall provide to the Secretary the name and telephone number of the individual responsible for responding to a request for information respecting drug samples.

(4) In this subsection, the term “authorized distributors of record” means those distributors with whom a manufacturer has established an ongoing relationship to distribute such manufacturer’s products.

(e) Wholesale distributors; guidelines for licensing; definitions

(1) Requirement

Subject to [section 360eee-2](#) of this title:

(A) In general

No person may engage in wholesale distribution of a drug subject to subsection (b)(1) in any State unless such person--

(i)(I) is licensed by the State from which the drug is distributed; or

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(II) if the State from which the drug is distributed has not established a licensure requirement, is licensed by the Secretary; and

(ii) if the drug is distributed interstate, is licensed by the State into which the drug is distributed if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State.

(B) Standards

Each Federal and State license described in subparagraph (A) shall meet the standards, terms, and conditions established by the Secretary under [section 360eee-2](#) of this title.

(2) Reporting and database

(A) Reporting

Beginning January 1, 2015, any person who owns or operates an establishment that engages in wholesale distribution shall--

(i) report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary--

(I) each State by which the person is licensed and the appropriate identification number of each such license; and

(II) the name, address, and contact information of each facility at which, and all trade names under which, the person conducts business; and

(ii) report to the Secretary within a reasonable period of time and in a reasonable manner, as determined by the Secretary, any significant disciplinary actions, such as the revocation or suspension of a wholesale distributor license, taken by a State or the Federal Government during the reporting period against the wholesale distributor.

(B) Database

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Not later than January 1, 2015, the Secretary shall establish a database of authorized wholesale distributors. Such database shall--

(i) identify each authorized wholesale distributor by name, contact information, and each State where such wholesale distributor is appropriately licensed to engage in wholesale distribution;

(ii) be available to the public on the Internet Web site of the Food and Drug Administration; and

(iii) be regularly updated on a schedule determined by the Secretary.

(C) Coordination

The Secretary shall establish a format and procedure for appropriate State officials to access the information provided pursuant to subparagraph (A) in a prompt and secure manner.

(D) Confidentiality

Nothing in this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to [section 552\(b\)\(4\) of Title 5](#), or [section 1905 of Title 18](#).

(3) Costs

(A) Authorized fees of Secretary

If a State does not establish a licensing program for persons engaged in the wholesale distribution of a drug subject to subsection (b), the Secretary shall license a person engaged in wholesale distribution located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

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(B) State licensing fees

Nothing in this chapter shall prohibit States from collecting fees from wholesale distributors in connection with State licensing of such distributors.

(4) For the purposes of this subsection and subsection (d), the term “wholesale distribution” means the distribution of a drug subject to subsection (b) to a person other than a consumer or patient, or receipt of a drug subject to subsection (b) by a person other than the consumer or patient, but does not include--

(A) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

(B) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

(C) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to [section 247d of Title 42](#), except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(D) the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b)(1);

(E) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

(F) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(G) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

(H) the distribution of a drug by the manufacturer of such drug;

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(I) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

(J) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

(K) the distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with [section 360eee-1\(e\)](#) of this title;

(L) salable drug returns when conducted by a dispenser;

(M) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a “medical convenience kit”) if--

(i) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with [section 360\(b\)\(2\)](#) of this title;

(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

(iii) in the case of a medical convenience kit that includes a product, the person that manufactures the kit--

(I) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

(II) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(iv) in the case of a medical convenience kit that includes a product, the product is--

(I) an intravenous solution intended for the replenishment of fluids and electrolytes;

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(II) a product intended to maintain the equilibrium of water and minerals in the body;

(III) a product intended for irrigation or reconstitution;

(IV) an anesthetic;

(V) an anticoagulant;

(VI) a vasopressor; or

(VII) a sympathomimetic;

(N) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(O) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(P) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(Q) the distribution of medical gas, as defined in [section 360ddd](#) of this title;

(R) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

(S) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in [section 360eee\(16\)\(B\)](#) of

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this title and registered under [section 360](#) of this title for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.

(5) Third-party logistics providers

Notwithstanding paragraphs (1) through (4), each entity that meets the definition of a third-party logistics provider under [section 360eee\(22\)](#) of this title shall obtain a license as a third-party logistics provider as described in [section 360eee-3\(a\)](#) of this title and is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles.

(6) Affiliate

For purposes of this subsection, the term “affiliate” means a business entity that has a relationship with a second business entity if, directly or indirectly--

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has the power to control, both of the business entities.

(f) Veterinary prescription drugs

(1)(A) A drug intended for use by animals other than man, other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug, which--

(i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or

(ii) is limited by an approved application under [subsection \(b\) of section 360b](#) of this title, a conditionally-approved application under [section 360ccc](#) of this title, or an index listing under [section 360ccc-1](#) of this title to use under the professional supervision of a licensed veterinarian,

shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the

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veterinarian's professional practice.

(B) For purposes of subparagraph (A), an order is lawful if the order--

(i) is a prescription or other order authorized by law,

(ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person, and

(iii) is refilled only if authorized in the original order or in a subsequent oral order promptly reduced to writing by the person lawfully filling the order, and filed by that person.

(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug when dispensed in accordance with paragraph (1) of this subsection--

(A) shall be exempt from the requirements of [section 352](#) of this title, except subsections (a), (g), (h), (i)(2), (i)(3), and (p) of such section, and

(B) shall be exempt from the packaging requirements of subsections (g), (h), and (p) of such section, if--

(i) when dispensed by a licensed veterinarian, the drug bears a label containing the name and address of the practitioner and any directions for use and cautionary statements specified by the practitioner, or

(ii) when dispensed by filling the lawful order of a licensed veterinarian, the drug bears a label containing the name and address of the dispenser, the serial number and date of the order or of its filling, the name of the licensed veterinarian, and the directions for use and cautionary statements, if any, contained in such order.

The preceding sentence shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail.

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(3) The Secretary may by regulation exempt drugs for animals other than man subject to [section 360b](#), [360ccc](#), or [360ccc-1](#) of this title from the requirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.”. A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the statement specified in the preceding sentence.

(g) Regulation of combination products

(1) The Secretary shall in accordance with this subsection assign an agency center to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of--

(A) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the agency center charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.

(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

(3) The Secretary shall promulgate regulations to implement market clearance procedures in accordance with paragraphs (1) and (2) not later than 1 year after November 28, 1990.

(4)(A) Not later than 60 days after October 26, 2002, the Secretary shall establish within the Office of the Commissioner of Food and Drugs an office to ensure the prompt assignment of combination products to agency centers, the timely and effective premarket review of such products, and consistent and appropriate postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law. Additionally, the office shall, in determining whether a product is to be designated a combination product, consult with the component within the Office of the Commissioner of

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Food and Drugs that is responsible for such determinations. Such office (referred to in this paragraph as the “Office”) shall have appropriate scientific and medical expertise, and shall be headed by a director.

(B) In carrying out this subsection, the Office shall, for each combination product, promptly assign an agency center with primary jurisdiction in accordance with paragraph (1) for the premarket review of such product.

(C)(i) In carrying out this subsection, the Office shall ensure timely and effective premarket reviews by overseeing the timeliness of and coordinating reviews involving more than one agency center.

(ii) In order to ensure the timeliness of the premarket review of a combination product, the agency center with primary jurisdiction for the product, and the consulting agency center, shall be responsible to the Office with respect to the timeliness of the premarket review.

(D) In carrying out this subsection, the Office shall ensure the consistency and appropriateness of postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law.

(E)(i) Any dispute regarding the timeliness of the premarket review of a combination product may be presented to the Office for resolution, unless the dispute is clearly premature.

(ii) During the review process, any dispute regarding the substance of the premarket review may be presented to the Commissioner of Food and Drugs after first being considered by the agency center with primary jurisdiction of the premarket review, under the scientific dispute resolution procedures for such center. The Commissioner of Food and Drugs shall consult with the Director of the Office in resolving the substantive dispute.

(F) The Secretary, acting through the Office, shall review each agreement, guidance, or practice of the Secretary that is specific to the assignment of combination products to agency centers and shall determine whether the agreement, guidance, or practice is consistent with the requirements of this subsection. In carrying out such review, the Secretary shall consult with stakeholders and the directors of the agency centers. After such consultation, the Secretary shall determine whether to continue in effect, modify, revise, or eliminate such agreement, guidance, or practice, and shall publish in the Federal Register a notice of the availability of such modified or revised agreement, guidance or practice. Nothing in this paragraph shall be construed as preventing the Secretary from following each agreement, guidance, or practice until continued, modified, revised, or eliminated.

(G) Not later than one year after October 26, 2002 and annually thereafter, the Secretary shall report to the appropriate committees of Congress on the activities and impact of the Office. The report shall include provisions--

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- (i) describing the numbers and types of combination products under review and the timeliness in days of such assignments, reviews, and dispute resolutions;
 - (ii) identifying the number of premarket reviews of such products that involved a consulting agency center; and
 - (iii) describing improvements in the consistency of postmarket regulation of combination products.
- (H) Nothing in this paragraph shall be construed to limit the regulatory authority of any agency center.
- (5) As used in this subsection:
- (A) The term “agency center” means a center or alternative organizational component of the Food and Drug Administration.
 - (B) The term “biological product” has the meaning given the term in [section 262\(i\) of Title 42](#).
 - (C) The term “market clearance” includes--
 - (i) approval of an application under [section 355, 357, 360e, or 360j\(g\)](#) of this title,
 - (ii) a finding of substantial equivalence under this part, and
 - (iii) approval of a biologics license application under [subsection \(a\) of section 262 of Title 42](#).

CREDIT(S)

(June 25, 1938, c. 675, § 503, 52 Stat. 1051; 1940 Reorg. Plan No. IV, § 12, eff. June 30, 1940, 5 F.R. 2422, 54 Stat. 1237; Oct. 26, 1951, c. 578, § 1, 65 Stat. 648; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 10, 1962, Pub.L. 87-781, Title I, § 104(e)(2), 76 Stat. 785; Dec. 30, 1970, Pub.L. 91-601, § 6(e), formerly § 7(e), 84 Stat. 1673;

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renumbered § 6(e), Aug. 13, 1981, [Pub.L. 97-35, Title XII, § 1205\(c\)](#), 95 Stat. 716; Apr. 22, 1988, [Pub.L. 100-293, §§ 4 to 6](#), 102 Stat. 96 to 98; Nov. 16, 1988, [Pub.L. 100-670, Title I, § 105](#), 102 Stat. 3983; Nov. 28, 1990, [Pub.L. 101-629, § 16\(a\)](#), 104 Stat. 4526; Aug. 17, 1991, [Pub.L. 102-108, § 2\(d\)](#), 105 Stat. 550; June 16, 1992, [Pub.L. 102-300, § 6\(d\)](#), 106 Stat. 240; Aug. 26, 1992, [Pub.L. 102-353, §§ 2\(a\) to \(c\)](#), 4, 106 Stat. 941, 942; Oct. 9, 1996, [Pub.L. 104-250, § 5\(a\)](#), 110 Stat. 3155; Nov. 21, 1997, [Pub.L. 105-115, Title I, §§ 123\(e\)](#), 126(a), (c)(1), (2), 111 Stat. 2324, 2327, 2328; Oct. 26, 2002, [Pub.L. 107-250, Title II, § 204](#), 116 Stat. 1611; Aug. 2, 2004, [Pub.L. 108-282, Title I, § 102\(b\)\(5\)\(F\)](#), 118 Stat. 903; [Pub.L. 113-54, Title II, § 204\(a\)\(1\) to \(4\), \(b\)](#), Nov. 27, 2013, 127 Stat. 630, 635.)

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§ 801. Congressional findings and declarations: controlled substances, 21 USCA § 801

United States Code Annotated

Title 21. Food and Drugs (Refs & Annos)

Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)
--

Subchapter I. Control and Enforcement

Part A. Introductory Provisions (Refs & Annos)
--

21 U.S.C.A. § 801

§ 801. Congressional findings and declarations: controlled substances

Currentness

The Congress makes the following findings and declarations:

- (1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.
- (2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.
- (3) A major portion of the traffic in controlled substances flows through interstate and foreign commerce. Incidents of the traffic which are not an integral part of the interstate or foreign flow, such as manufacture, local distribution, and possession, nonetheless have a substantial and direct effect upon interstate commerce because--
 - (A) after manufacture, many controlled substances are transported in interstate commerce,
 - (B) controlled substances distributed locally usually have been transported in interstate commerce immediately before their distribution, and
 - (C) controlled substances possessed commonly flow through interstate commerce immediately prior to such possession.
- (4) Local distribution and possession of controlled substances contribute to swelling the interstate traffic in such substances.

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(5) Controlled substances manufactured and distributed intrastate cannot be differentiated from controlled substances manufactured and distributed interstate. Thus, it is not feasible to distinguish, in terms of controls, between controlled substances manufactured and distributed interstate and controlled substances manufactured and distributed intrastate.

(6) Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.

(7) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances.

CREDIT(S)

(Pub.L. 91-513, Title II, § 101, Oct. 27, 1970, 84 Stat. 1242.)

EXECUTIVE ORDERS**EXECUTIVE ORDER NO. 11599**

Ex. Ord. No. 11599, June 17, 1971, 36 F.R. 11793, formerly set out as a note under this section, which established the Special Action Office for Drug Abuse Prevention, was superseded by former section 1111 et seq. of this title and is now covered by [section 1111 et seq.](#) of this title, which established the Office of Drug Abuse Policy.

EXECUTIVE ORDER NO. 11641

Ex. Ord. No. 11641, Jan. 28, 1972, 37 F.R. 2421, formerly set out as a note under this section, which established the Office for Drug Abuse Law Enforcement, was revoked by Ex. Ord. No. 11727, July 6, 1973, 38 F.R. 18357, set out below.

EXECUTIVE ORDER NO. 11676

Ex. Ord. No. 11676, July 27, 1972, 37 F.R. 15125, formerly set out as a note under this section, which established the Office of National Narcotics Intelligence, was revoked by [Ex. Ord. No. 11727](#), July 6, 1973, 38 F.R. 18357 set out below.

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EXECUTIVE ORDER NO. 11727

<July 6, 1973, 38 F.R. 18357>

DRUG LAW ENFORCEMENT

Reorganization Plan No. 2 of 1973 [set out in the Appendix to Title 5, Government Organization and Employees], which becomes effective on July 1, 1973, among other things establishes a Drug Enforcement Administration in the Department of Justice. In my message to the Congress transmitting that plan, I stated that all functions of the Office for Drug Abuse Law Enforcement (established pursuant to Executive Order No. 11641 of January 28, 1972) and the Office of National Narcotics Intelligence (established pursuant to Executive Order No. 11676 of July 27, 1972) would, together with other related functions, be merged in the new Drug Enforcement Administration.

NOW, THEREFORE, by virtue of the authority vested in me by the Constitution and laws of the United States, including section 5317 of title 5 of the United States Code, as amended [section 5317 of Title 5, Government Organization and Employees], it is hereby ordered as follows:

Section 1. The Attorney General, to the extent permitted by law, is authorized to coordinate all activities of executive branch departments and agencies which are directly related to the enforcement of laws respecting narcotics and dangerous drugs. Each department and agency of the Federal Government shall, upon request and to the extent permitted by law, assist the Attorney General in the performance of functions assigned to him pursuant to this order, and the Attorney General may, in carrying out those functions, utilize the services of any other agencies, Federal and State, as may be available and appropriate.

Sec. 2. Executive Order No. 11641 of January 28, 1972, is revoked and the Attorney General shall provide for the reassignment of the functions of the Office for Drug Abuse Law Enforcement and for the abolishment of that Office.

Sec. 3. Executive Order No. 11676 of July 27, 1972, is hereby revoked and the Attorney General shall provide for the reassignment of the functions of the Office of National Narcotics Intelligence and for the abolishment of that Office.

Sec. 4. Section 1 of Executive Order No. 11708 of March 23, 1973, as amended [set out as a note under section 5317 of Title 5, Government Organization and Employees], placing certain positions in level IV of the Executive Schedule is hereby further amended by deleting--

(1) “(6) Director, Office for Drug Abuse Law Enforcement, Department of Justice.”; and

(2) “(7) Director, Office of National Narcotics Intelligence, Department of Justice.”

Sec. 5. The Attorney General shall provide for the winding up of the affairs of the two offices and for the reassignment of

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their functions.

Sec. 6. This order shall be effective as of July 1, 1973.

RICHARD NIXON


21 U.S.C.A. § 801, 21 USCA § 801

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§ 802. Definitions, 21 USCA § 802

 KeyCite Yellow Flag - Negative Treatment
 Unconstitutional or Preempted **Prior Version Held Unconstitutional as Applied by U.S. v. Roberts**, S.D.N.Y., Sep. 09, 2002
 KeyCite Yellow Flag - Negative Treatment Proposed Legislation

United States Code Annotated**Title 21. Food and Drugs (Refs & Annos)****Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)****Subchapter I. Control and Enforcement****Part A. Introductory Provisions (Refs & Annos)**

21 U.S.C.A. § 802

§ 802. Definitions

Effective: December 18, 2014

[Currentness](#)

As used in this subchapter:

(1) The term “addict” means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction.

(2) The term “administer” refers to the direct application of a controlled substance to the body of a patient or research subject by--

(A) a practitioner (or, in his presence, by his authorized agent), or

(B) the patient or research subject at the direction and in the presence of the practitioner,

whether such application be by injection, inhalation, ingestion, or any other means.

(3) The term “agent” means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser; except that such term does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier’s or warehouseman’s business.

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(4) The term “Drug Enforcement Administration” means the Drug Enforcement Administration in the Department of Justice.

(5) The term “control” means to add a drug or other substance, or immediate precursor, to a schedule under part B of this subchapter, whether by transfer from another schedule or otherwise.

(6) The term “controlled substance” means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of this subchapter. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

(7) The term “counterfeit substance” means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.

(8) The terms “deliver” or “delivery” mean the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.

(9) The term “depressant or stimulant substance” means--

(A) a drug which contains any quantity of barbituric acid or any of the salts of barbituric acid; or

(B) a drug which contains any quantity of (i) amphetamine or any of its optical isomers; (ii) any salt of amphetamine or any salt of an optical isomer of amphetamine; or (iii) any substance which the Attorney General, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system; or

(C) lysergic acid diethylamide; or

(D) any drug which contains any quantity of a substance which the Attorney General, after investigation, has found to have, and by regulation designated as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect.

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(10) The term “dispense” means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term “dispenser” means a practitioner who so delivers a controlled substance to an ultimate user or research subject.

(11) The term “distribute” means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term “distributor” means a person who so delivers a controlled substance or a listed chemical.

(12) The term “drug” has the meaning given that term by [section 321\(g\)\(1\)](#) of this title.

(13) The term “felony” means any Federal or State offense classified by applicable Federal or State law as a felony.

(14) The term “isomer” means the optical isomer, except as used in schedule I(c) and schedule II(a)(4). As used in schedule I(c), the term “isomer” means any optical, positional, or geometric isomer. As used in schedule II(a)(4), the term “isomer” means any optical or geometric isomer.

(15) The term “manufacture” means the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container; except that such term does not include the preparation, compounding, packaging, or labeling of a drug or other substance in conformity with applicable State or local law by a practitioner as an incident to his administration or dispensing of such drug or substance in the course of his professional practice. The term “manufacturer” means a person who manufactures a drug or other substance.

(16) The term “marihuana” means all parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

(17) The term “narcotic drug” means any of the following whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific

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chemical designation. Such term does not include the isoquinoline alkaloids of opium.

(B) Poppy straw and concentrate of poppy straw.

(C) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed.

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers.

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers.

(F) Any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subparagraphs (A) through (E).

(18) The term “opiate” means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

(19) The term “opium poppy” means the plant of the species *Papaver somniferum* L., except the seed thereof.

(20) The term “poppy straw” means all parts, except the seeds, of the opium poppy, after mowing.

(21) The term “practitioner” means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(22) The term “production” includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(23) The term “immediate precursor” means a substance--

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(A) which the Attorney General has found to be and by regulation designated as being the principal compound used, or produced primarily for use, in the manufacture of a controlled substance;

(B) which is an immediate chemical intermediary used or likely to be used in the manufacture of such controlled substance; and

(C) the control of which is necessary to prevent, curtail, or limit the manufacture of such controlled substance.

(24) The term “Secretary”, unless the context otherwise indicates, means the Secretary of Health and Human Services.

(25) The term “serious bodily injury” means bodily injury which involves--

(A) a substantial risk of death;

(B) protracted and obvious disfigurement; or

(C) protracted loss or impairment of the function of a bodily member, organ, or mental faculty.

(26) The term “State” means a State of the United States, the District of Columbia, and any commonwealth, territory, or possession of the United States.

(27) The term “ultimate user” means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.

(28) The term “United States”, when used in a geographic sense, means all places and waters, continental or insular, subject to the jurisdiction of the United States.

(29) The term “maintenance treatment” means the dispensing, for a period in excess of twenty-one days, of a narcotic drug

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in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

(30) The term “detoxification treatment” means the dispensing, for a period not in excess of one hundred and eighty days, of a narcotic drug in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period.

(31) The term “Convention on Psychotropic Substances” means the Convention on Psychotropic Substances signed at Vienna, Austria, on February 21, 1971; and the term “Single Convention on Narcotic Drugs” means the Single Convention on Narcotic Drugs signed at New York, New York, on March 30, 1961.

(32)(A) Except as provided in subparagraph (C), the term “controlled substance analogue” means a substance--

(i) the chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;

(ii) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

(iii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II.

(B) The designation of gamma butyrolactone or any other chemical as a listed chemical pursuant to paragraph (34) or (35) does not preclude a finding pursuant to subparagraph (A) of this paragraph that the chemical is a controlled substance analogue.

(C) Such term does not include--

(i) a controlled substance;

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(ii) any substance for which there is an approved new drug application;

(iii) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under [section 355](#) of this title to the extent conduct with respect to such substance is pursuant to such exemption; or

(iv) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

(33) The term “listed chemical” means any list I chemical or any list II chemical.

(34) The term “list I chemical” means a chemical specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this subchapter and is important to the manufacture of the controlled substances, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following:

(A) Anthranilic acid, its esters, and its salts.

(B) Benzyl cyanide.

(C) Ephedrine, its salts, optical isomers, and salts of optical isomers.

(D) Ergonovine and its salts.

(E) Ergotamine and its salts.

(F) N-Acetylanthranilic acid, its esters, and its salts.

(G) Norpseudoephedrine, its salts, optical isomers, and salts of optical isomers.

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(H) Phenylacetic acid, its esters, and its salts.

(I) Phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.

(J) Piperidine and its salts.

(K) Pseudoephedrine, its salts, optical isomers, and salts of optical isomers.

(L) 3,4-Methylenedioxyphenyl-2-propanone.

(M) Methylamine.

(N) Ethylamine.

(O) Propionic anhydride.

(P) Isosafrole.

(Q) Safrole.

(R) Piperonal.

(S) N-Methylephedrine.

(T) N-methylpseudoephedrine.

(U) Hydriodic acid.

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(V) Benzaldehyde.

(W) Nitroethane.

(X) Gamma butyrolactone.

(Y) Any salt, optical isomer, or salt of an optical isomer of the chemicals listed in subparagraphs (M) through (U) of this paragraph.

(35) The term “list II chemical” means a chemical (other than a list I chemical) specified by regulation of the Attorney General as a chemical that is used in manufacturing a controlled substance in violation of this subchapter, and such term includes (until otherwise specified by regulation of the Attorney General, as considered appropriate by the Attorney General or upon petition to the Attorney General by any person) the following chemicals:

(A) Acetic anhydride.

(B) Acetone.

(C) Benzyl chloride.

(D) Ethyl ether.

(E) Repealed. [Pub.L. 101-647, Title XXIII, § 2301\(b\)](#), Nov. 29, 1990, 104 Stat. 4858.

(F) Potassium permanganate.

(G) 2-Butanone (or Methyl Ethyl Ketone).

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(H) Toluene.

(I) Iodine.

(J) Hydrochloric gas.

(36) The term “regular customer” means, with respect to a regulated person, a customer with whom the regulated person has an established business relationship that is reported to the Attorney General.

(37) The term “regular importer” means, with respect to a listed chemical, a person that has an established record as an importer of that listed chemical that is reported to the Attorney General.

(38) The term “regulated person” means a person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

(39) The term “regulated transaction” means--

(A) a distribution, receipt, sale, importation, or exportation of, or an international transaction involving shipment of, a listed chemical, or if the Attorney General establishes a threshold amount for a specific listed chemical, a threshold amount, including a cumulative threshold amount for multiple transactions (as determined by the Attorney General, in consultation with the chemical industry and taking into consideration the quantities normally used for lawful purposes), of a listed chemical, except that such term does not include--

(i) a domestic lawful distribution in the usual course of business between agents or employees of a single regulated person;

(ii) a delivery of a listed chemical to or by a common or contract carrier for carriage in the lawful and usual course of the business of the common or contract carrier, or to or by a warehouseman for storage in the lawful and usual course of the business of the warehouseman, except that if the carriage or storage is in connection with the distribution, importation, or exportation of a listed chemical to a third person, this clause does not relieve a distributor, importer, or exporter from compliance with [section 830](#) of this title;

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(iii) any category of transaction or any category of transaction for a specific listed chemical or chemicals specified by regulation of the Attorney General as excluded from this definition as unnecessary for enforcement of this subchapter or subchapter II of this chapter;

(iv) any transaction in a listed chemical that is contained in a drug that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act, subject to clause (v), unless--

(I) the Attorney General has determined under [section 814](#) of this title that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(II) the quantity of the listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical by the Attorney General;

(v) any transaction in a scheduled listed chemical product that is a sale at retail by a regulated seller or a distributor required to submit reports under [section 830\(b\)\(3\)](#) of this title; or

(vi) any transaction in a chemical mixture which the Attorney General has by regulation designated as exempt from the application of this subchapter and subchapter II of this chapter based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered; and

(B) a distribution, importation, or exportation of a tableting machine or encapsulating machine.

(40) The term “chemical mixture” means a combination of two or more chemical substances, at least one of which is not a list I chemical or a list II chemical, except that such term does not include any combination of a list I chemical or a list II chemical with another chemical that is present solely as an impurity.

(41)(A) The term “anabolic steroid” means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone), and includes

(i) androstenediol--

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(I) 3 β ,17 β -dihydroxy-5 α - androstane; and

(II) 3 α ,17 β -dihydroxy-5 α - androstane;

(ii) androstanedione (5 α -androstan-3,17-dione);

(iii) androstenediol--

(I) 1-androstenediol (3 β ,17 β -dihydroxy-5 α -androst-1-ene);

(II) 1-androstenediol (3 α ,17 β -dihydroxy-5 α -androst-1-ene);

(III) 4-androstenediol (3 β ,17 β -dihydroxy-androst-4-ene); and

(IV) 5-androstenediol (3 β ,17 β -dihydroxy-androst-5-ene);

(iv) androstenedione--

(I) 1-androstenedione ([5 α]-androst-1-en-3,17-dione);

(II) 4-androstenedione (androst-4-en-3,17-dione); and

(III) 5-androstenedione (androst-5-en-3,17-dione);

(v) bolasterone (7 α ,17 α - dimethyl-17 β -hydroxyandrost-4-en-3-one);

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- (vi) boldenone (17 β -hydroxyandrost-1,4,-diene-3-one);
- (vii) calusterone (7 β , 17 α -dimethyl-17 β -hydroxyandrost-4-en-3-one);
- (viii) clostebol (4-chloro-17 β -hydroxyandrost-4-en-3-one);
- (ix) dehydrochloromethyltestosterone (4-chloro-17 β -hydroxy-17 α -methyl-androst-1, 4-dien-3-one);
- (x) Δ 1-dihydrotestosterone (a.k.a. “1-testosterone”) (17 β -hydroxy-5 α -androst-1-en-3-one);
- (xi) 4-dihydrotestosterone (17 β -hydroxy-androstan-3-one);
- (xii) drostanolone (17 β -hydroxy-2 α - methyl-5 α -androstan-3-one);
- (xiii) ethylestrenol (17 α -ethyl-17 β -hydroxyestr-4-ene);
- (xiv) fluoxymesterone (9-fluoro-17 α -methyl-11 β , 17 β -dihydroxyandrost-4-en-3-one);
- (xv) formebolone (2-formyl-17 α -methyl-11 α , 17 β -dihydroxyandrost-1,4-dien-3-one);
- (xvi) furazabol (17 α -methyl-17 β -hydroxyandrostano[2,3-c]-furazan);
- (xvii) 13 β -ethyl-17 β -hydroxygon-4-en-3-one;
- (xviii) 4-hydroxytestosterone (4,17 β -dihydroxy-androst-4-en-3-one);
- (xix) 4-hydroxy-19-nortestosterone (4,17 β -dihydroxy-estr-4-en-3-one);

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(xx) mestanolone (17 α -methyl- 17 β -hydroxy-5 α -androstan-3-one);

(xxi) mesterolone (1 α -methyl-17 β -hydroxy-[5 α] -androstan-3-one);

(xxii) methandienone (17 α -methyl-17 β -hydroxyandrost-1,4-dien-3-one);

(xxiii) methandriol (17 α -methyl- 3 β ,17 β -dihydroxyandrost-5-ene);

(xxiv) methenolone (1-methyl-17 β -hydroxy-5 α -androst-1-en-3-one);

(xxv) 17 α -methyl-3 β , 17 β -dihydroxy-5 α -androstane;

(xxvi) 17 α -methyl-3 α , 17 β -dihydroxy-5 α -androstane;

(xxvii) 17 α -methyl-3 β , 17 β -dihydroxyandrost-4-ene.

(xxviii) 17 α -methyl-4-hydroxynandrolone (17 α -methyl-4-hydroxy-17 β -hydroxyestr-4-en-3-one);

(xxix) methyldienolone (17 α -methyl-17 β -hydroxyestra-4,9(10)-dien-3-one);

(xxx) methyltrienolone (17 α -methyl-17 β -hydroxyestra-4,9-11-trien-3-one);

(xxxi) methyltestosterone (17 α -methyl-17 β -hydroxyandrost-4-en-3-one);

(xxxii) mibolerone (7 α , 17 α -dimethyl-17 β -hydroxyestr-4-en-3-one);

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(xxxiii) 17α -methyl- Δ 1-dihydrotestosterone (17β -hydroxy- 17α -methyl- 5α -androst-1-en-3-one) (a.k.a. “17- α -methyl-1-testosterone”);

(xxxiv) nandrolone (17β -hydroxyestr-4-en-3-one);

(xxxv) norandrostenediol--

(I) 19-nor-4-androstenediol (3β , 17β -dihydroxyestr-4-ene);

(II) 19-nor-4-androstenediol (3α , 17β -dihydroxyestr-4-ene);

(III) 19-nor-5-androstenediol (3β , 17β -dihydroxyestr-5-ene); and

(IV) 19-nor-5-androstenediol (3α , 17β -dihydroxyestr-5-ene);

(xxxvi) norandrostenedione--

(I) 19-nor-4-androstenedione (estr-4-en-3,17-dione); and

(II) 19-nor-5-androstenedione (estr-5-en-3,17-dione);

(xxxvii) norbolethone (13β , 17α -diethyl- 17β -hydroxygon-4-en-3-one);

(xxxviii) norclostebol (4-chloro- 17β -hydroxyestr-4-en-3-one);

(xxxix) norethandrolone (17α -ethyl- 17β -hydroxyestr-4-en-3-one);

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(**xl**) normethandrolone (17 α -methyl-17 β -hydroxyestr-4-en-3-one);

(**xli**) oxandrolone (17 α -methyl-17 β -hydroxy-2-oxa-[5 α]- androstan-3-one);

(**xlii**) oxymesterone (17 α -methyl-4,17 β -dihydroxyandrost-4-en-3-one);

(**xliii**) oxymetholone (17 α -methyl-2-hydroxymethylene-17 β -hydroxy- [5 α]-androstan-3-one);

(**xliv**) stanozolol (17 α -methyl- 17 β -hydroxy-[5 α]-androst-2-eno[3,2-c]-pyrazole);

(**xliv**) stenbolone (17 β -hydroxy-2-methyl-[5 α] -androst-1-en-3-one);

(**xlvi**) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);

(**xlvi**) testosterone (17 β -hydroxyandrost-4-en-3-one);

(**xlvi**) tetrahydrogestrinone (13 β ,17 α -diethyl-17 β -hydroxygon-4,9, 11-trien-3-one);

(**xlix**) trenbolone (17 β -hydroxyestr-4,9,11-trien-3-one);

(**i**) 5 α -Androstan-3,6,17-trione;

(**ii**) 6-bromo-androstan-3,17-dione;

(**iii**) 6-bromo-androsta-1,4-diene-3,17-dione;

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- (liii) 4-chloro-17 α -methyl-androsta-1,4-diene-3,17 β -diol;
- (liv) 4-chloro-17 α -methyl-androst-4-ene-3 β ,17 β -diol;
- (lv) 4-chloro-17 α -methyl-17 β -hydroxy-androst-4-en-3-one;
- (lvi) 4-chloro-17 α -methyl-17 β -hydroxy-androst-4-ene-3,11-dione;
- (lvii) 4-chloro-17 α -methyl-androsta-1,4-diene-3,17 β -diol;
- (lviii) 2 α ,17 α -dimethyl-17 β -hydroxy-5 α -androstan-3-one;
- (lix) 2 α ,17 α -dimethyl-17 β -hydroxy-5 β -androstan-3-one;
- (lx) 2 α ,3 α -epithio-17 α -methyl-5 α -androstan-17 β -ol;
- (lxi) [3,2-c]-furazan-5 α -androstan-17 β -ol;
- (lxii) 3 β -hydroxy-estra-4,9,11-trien-17-one;
- (lxiii) 17 α -methyl-androst-2-ene-3,17 β -diol;
- (lxiv) 17 α -methyl-androsta-1,4-diene-3,17 β -diol;
- (lxv) Estra-4,9,11-triene-3,17-dione;
- (lxvi) 18 α -Homo-3-hydroxy-estra-2,5(10)-dien-17-one;

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(**lxvii**) 6 α -Methyl-androst-4-ene-3,17-dione;

(**lxviii**) 17 α -Methyl-androstan-3-hydroxyimine-17 β -ol;

(**lxix**) 17 α -Methyl-5 α -androstan-17 β -ol;

(**lxx**) 17 β -Hydroxy-androstano[2,3-d]isoxazole;

(**lxxi**) 17 β -Hydroxy-androstano[3,2-c]isoxazole;

(**lxxii**) 4-Hydroxy-androst-4-ene-3,17-dione[3,2-c]pyrazole-5 α -androstan-17 β -ol;

(**lxxiii**) [3,2-c]pyrazole-androst-4-en-17 β -ol;

(**lxxiv**) [3,2-c]pyrazole-5 α -androstan-17 β -ol; and

(**lxxv**) any salt, ester, or ether of a drug or substance described in this paragraph.

The substances excluded under this subparagraph may at any time be scheduled by the Attorney General in accordance with the authority and requirements of [subsections \(a\) through \(c\) of section 811](#) of this title.

(**B**)(**i**) Except as provided in clause (ii), such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration.

(**ii**) If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of subparagraph (A).

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(C)(i) Subject to clause (ii), a drug or hormonal substance (other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone) that is not listed in subparagraph (A) and is derived from, or has a chemical structure substantially similar to, 1 or more anabolic steroids listed in subparagraph (A) shall be considered to be an anabolic steroid for purposes of this chapter if--

(I) the drug or substance has been created or manufactured with the intent of producing a drug or other substance that either--

(aa) promotes muscle growth; or

(bb) otherwise causes a pharmacological effect similar to that of testosterone; or

(II) the drug or substance has been, or is intended to be, marketed or otherwise promoted in any manner suggesting that consuming it will promote muscle growth or any other pharmacological effect similar to that of testosterone.

(ii) A substance shall not be considered to be a drug or hormonal substance for purposes of this subparagraph if it--

(I) is--

(aa) an herb or other botanical;

(bb) a concentrate, metabolite, or extract of, or a constituent isolated directly from, an herb or other botanical; or

(cc) a combination of 2 or more substances described in item (aa) or (bb);

(II) is a dietary ingredient for purposes of the Federal Food, Drug, and Cosmetic Act ([21 U.S.C. 301 et seq.](#)); and

(III) is not anabolic or androgenic.

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(iii) In accordance with [section 885\(a\)](#) of this title, any person claiming the benefit of an exemption or exception under clause (ii) shall bear the burden of going forward with the evidence with respect to such exemption or exception.

(42) The term “international transaction” means a transaction involving the shipment of a listed chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.

(43) The terms “broker” and “trader” mean a person that assists in arranging an international transaction in a listed chemical by--

(A) negotiating contracts;

(B) serving as an agent or intermediary; or

(C) bringing together a buyer and seller, a buyer and transporter, or a seller and transporter.

(44) The term “felony drug offense” means an offense that is punishable by imprisonment for more than one year under any law of the United States or of a State or foreign country that prohibits or restricts conduct relating to narcotic drugs, marihuana, anabolic steroids, or depressant or stimulant substances.

(45)(A) The term “scheduled listed chemical product” means, subject to subparagraph (B), a product that--

(i) contains ephedrine, pseudoephedrine, or phenylpropanolamine; and

(ii) may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a nonprescription drug.

Each reference in clause (i) to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical.

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(B) Such term does not include a product described in subparagraph (A) if the product contains a chemical specified in such subparagraph that the Attorney General has under [section 811\(a\)](#) of this title added to any of the schedules under [section 812\(c\)](#) of this title. In the absence of such scheduling by the Attorney General, a chemical specified in such subparagraph may not be considered to be a controlled substance.

(46) The term “regulated seller” means a retail distributor (including a pharmacy or a mobile retail vendor), except that such term does not include an employee or agent of such distributor.

(47) The term “mobile retail vendor” means a person or entity that makes sales at retail from a stand that is intended to be temporary, or is capable of being moved from one location to another, whether the stand is located within or on the premises of a fixed facility (such as a kiosk at a shopping center or an airport) or whether the stand is located on unimproved real estate (such as a lot or field leased for retail purposes).

(48) The term “at retail”, with respect to the sale or purchase of a scheduled listed chemical product, means a sale or purchase for personal use, respectively.

(49)(A) The term “retail distributor” means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to ephedrine, pseudoephedrine, or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

(B) For purposes of this paragraph, entities are defined by reference to the Standard Industrial Classification (SIC) code, as follows:

(i) A grocery store is an entity within SIC code 5411.

(ii) A general merchandise store is an entity within SIC codes 5300 through 5399 and 5499.

(iii) A drug store is an entity within SIC code 5912.

(50) The term “Internet” means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.

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(51) The term “deliver, distribute, or dispense by means of the Internet” refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

(52) The term “online pharmacy”--

(A) means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet; and

(B) does not include--

(i) manufacturers or distributors registered under subsection (a), (b), (d), or (e) of section 823 of this title who do not dispense controlled substances to an unregistered individual or entity;

(ii) nonpharmacy practitioners who are registered under section 823(f) of this title and whose activities are authorized by that registration;

(iii) any hospital or other medical facility that is operated by an agency of the United States (including the Armed Forces), provided such hospital or other facility is registered under section 823(f) of this title;

(iv) a health care facility owned or operated by an Indian tribe or tribal organization, only to the extent such facility is carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act;

(v) any agent or employee of any hospital or facility referred to in clause (iii) or (iv), provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of health care facilities specified in clause (iv), only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such clause;

(vi) mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

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(vii) a person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States;

(viii) a pharmacy registered under [section 823\(f\)](#) of this title whose dispensing of controlled substances via the Internet consists solely of--

(I) refilling prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (55); or

(II) filling new prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (56); or

(ix) any other persons for whom the Attorney General and the Secretary have jointly, by regulation, found it to be consistent with effective controls against diversion and otherwise consistent with the public health and safety to exempt from the definition of an “online pharmacy”.

(53) The term “homepage” means the opening or main page or screen of the website of an online pharmacy that is viewable on the Internet.

(54) The term “practice of telemedicine” means, for purposes of this subchapter, the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in [section 1395m\(m\)](#) of Title 42, which practice--

(A) is being conducted--

(i) while the patient is being treated by, and physically located in, a hospital or clinic registered under [section 823\(f\)](#) of this title; and

(ii) by a practitioner--

(I) acting in the usual course of professional practice;

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(II) acting in accordance with applicable State law; and

(III) registered under [section 823\(f\)](#) of this title in the State in which the patient is located, unless the practitioner--

(aa) is exempted from such registration in all States under [section 822\(d\)](#) of this title; or

(bb) is--

(AA) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

(BB) registered under [section 823\(f\)](#) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under [section 823\(f\)](#) of this title;

(B) is being conducted while the patient is being treated by, and in the physical presence of, a practitioner--

(i) acting in the usual course of professional practice;

(ii) acting in accordance with applicable State law; and

(iii) registered under [section 823\(f\)](#) of this title in the State in which the patient is located, unless the practitioner--

(I) is exempted from such registration in all States under [section 822\(d\)](#) of this title; or

(II) is--

(aa) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

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(bb) registered under [section 823\(f\)](#) of this title in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under [section 823\(f\)](#) of this title;

(C) is being conducted by a practitioner--

(i) who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act;

(ii) acting within the scope of the employment, contract, or compact described in clause (i); and

(iii) who is designated as an Internet Eligible Controlled Substances Provider by the Secretary under [section 831\(g\)\(2\)](#) of this title;

(D)(i) is being conducted during a public health emergency declared by the Secretary under [section 247d of Title 42](#); and

(ii) involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates, provided that such designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of Title 5;

(E) is being conducted by a practitioner who has obtained from the Attorney General a special registration under [section 831\(h\)](#) of this title;

(F) is being conducted--

(i) in a medical emergency situation--

(I) that prevents the patient from being in the physical presence of a practitioner registered under [section 823\(f\)](#) of this title who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;

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(II) that prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under [section 823\(f\)](#) of this title;

(III) during which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and

(IV) that requires immediate intervention by a health care practitioner using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death; and

(ii) by a practitioner that--

(I) is an employee or contractor of the Veterans Health Administration acting within the scope of that employment or contract;

(II) is registered under [section 823\(f\)](#) of this title in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under [section 823\(f\)](#) of this title; and

(III) issues a controlled substance prescription in this emergency context that is limited to a maximum of a 5-day supply which may not be extended or refilled; or

(G) is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

(55) The term “refilling prescriptions for controlled substances in schedule III, IV, or V”--

(A) means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of [subsections \(b\) and \(c\) of section 829](#) of this title, as appropriate; and

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(B) does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

(56) The term “filling new prescriptions for controlled substances in schedule III, IV, or V” means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if--

(A) the pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of subsections (b) and (c) of section 829 of this title (in this paragraph referred to as the “original prescription”);

(B) the pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in subparagraph (A); and

(C) the practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

CREDIT(S)

(Pub.L. 91-513, Title II, § 102, Oct. 27, 1970, 84 Stat. 1242; Pub.L. 93-281, § 2, May 14, 1974, 88 Stat. 124; Pub.L. 95-633, Title I, § 102(b), Nov. 10, 1978, 92 Stat. 3772; Pub.L. 96-88, Title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub.L. 96-132, § 16(a), Nov. 30, 1979, 93 Stat. 1049; Pub.L. 98-473, Title II, § 507(a), (b), Oct. 12, 1984, 98 Stat. 2071; Pub.L. 98-509, Title III, § 301(a), Oct. 19, 1984, 98 Stat. 2364; Pub.L. 99-514, § 2, Oct. 22, 1986, 100 Stat. 2095; Pub.L. 99-570, Title I, §§ 1003(b), 1203, 1870, Oct. 27, 1986, 100 Stat. 3207-6, 3207-13, 3207-56; Pub.L. 99-646, § 83, Nov. 10, 1986, 100 Stat. 3619; Pub.L. 100-690, Title VI, § 6054, Nov. 18, 1988, 102 Stat. 4316; Pub.L. 101-647, Title XIX, § 1902(b), Title XXIII, § 2301, Title XXXV, § 3599I, Nov. 29, 1990, 104 Stat. 4852, 4858, 4932; Pub.L. 103-200, §§ 2(a), 7 to 9(a), Dec. 17, 1993, 107 Stat. 2333, 2340; Pub.L. 103-322, Title IX, § 90105(d), Title XXXIII, § 330024(a), (b), (d)(1), Sept. 13, 1994, 108 Stat. 1988, 2150; Pub.L. 104-237, Title II, §§ 204(a), 209, Title IV, § 401(a), (b), Oct. 3, 1996, 110 Stat. 3102, 3104, 3106, 3107; Pub.L. 104-294, Title VI, §§ 604(b)(4), 607(j), Oct. 11, 1996, 110 Stat. 3506, 3512; Pub.L. 105-115, Title I, § 126(c)(3), Nov. 21, 1997, 111 Stat. 2328; Pub.L. 106-172, §§ 3(c), 5(a), Feb. 18, 2000, 114 Stat. 9, 10; Pub.L. 106-310, Div. B, Title XXXVI, § 3622(a), Oct. 17, 2000, 114 Stat. 1231; Pub.L. 107-273, Div. B, Title IV, § 4002(c)(1), Nov. 2, 2002, 116 Stat. 1808; Pub.L. 108-358, § 2(a), Oct. 22, 2004, 118 Stat. 1661; Pub.L. 109-162, Title XI, § 1180, Jan. 5, 2006, 119 Stat. 3126; Pub.L. 109-177, Title VII, §§ 711(a)(1), (2)(A), 712(a)(1), Mar. 9, 2006, 120 Stat. 256, 257, 263; Pub.L. 110-425, § 3(a), Oct. 15, 2008, 122 Stat. 4821; Pub.L. 113-260, § 2(a), Dec. 18, 2014, 128 Stat. 2929.)

21 U.S.C.A. § 802, 21 USCA § 802

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ADD96

§ 802. Definitions, 21 USCA § 802

ADD97**§ 812. Schedules of controlled substances, 21 USCA § 812**



KeyCite Yellow Flag - Negative Treatment

Unconstitutional or Preempted **Prior Version's Limitation Recognized by U.S. v. Macedo**, 7th Cir.(Ill.), Apr. 14, 2005

KeyCite Yellow Flag - Negative Treatment Proposed Legislation

United States Code Annotated**Title 21. Food and Drugs (Refs & Annos)****Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)****Subchapter I. Control and Enforcement****Part B. Authority to Control; Standards and Schedules****21 U.S.C.A. § 812****§ 812. Schedules of controlled substances****Effective: July 9, 2012**[Currentness](#)**(a) Establishment**

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) Schedule I--**(A)** The drug or other substance has a high potential for abuse.**(B)** The drug or other substance has no currently accepted medical use in treatment in the United States.

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(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) Schedule II--

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) Schedule III--

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) Schedule IV--

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to

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the drugs or other substances in schedule III.

(5) Schedule V--

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Initial schedules of controlled substances

Schedules I, II, III, IV, and V shall, unless and until amended¹ pursuant to [section 811](#) of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

Schedule I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol.

(2) Allylprodine.

(3) Alphacetylmethadol.²

(4) Alphameprodine.

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(5) Alphamethadol.

(6) Benzethidine.

(7) Betacetylmethadol.

(8) Betameprodine.

(9) Betamethadol.

(10) Betaprodine.

(11) Clonitazene.

(12) Dextromoramide.

(13) Dextrophan.

(14) Diampromide.

(15) Diethylthiambutene.

(16) Dimenoxadol.

(17) Dimepheptanol.

(18) Dimethylthiambutene.

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(19) Dioxaphetyl butyrate.

(20) Dipipanone.

(21) Ethylmethylthiambutene.

(22) Etonitazene.

(23) Etoxeridine.

(24) Furethidine.

(25) Hydroxypethidine.

(26) Ketobemidone.

(27) Levomoramide.

(28) Levophenacymorphan.

(29) Morpheridine.

(30) Noracymethadol.

(31) Norlevorphanol.

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(32) Normethadone.

(33) Norpipanone.

(34) Phenadoxone.

(35) Phenampromide.

(36) Phenomorphan.

(37) Phenoperidine.

(38) Piritramide.

(39) Proheptazine.

(40) Properidine.

(41) Racemoramide.

(42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine.

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(2) Acetyldihydrocodeine.

(3) Benzylmorphine.

(4) Codeine methylbromide.

(5) Codeine-N-Oxide.

(6) Cyprenorphine.

(7) Desomorphine.

(8) Dihydromorphine.

(9) Etorphine.

(10) Heroin.

(11) Hydromorphenol.

(12) Methyl-desorphine.

(13) Methylhydromorphine.

(14) Morphine methylbromide.

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(15) Morphine methylsulfonate.

(16) Morphine-N-Oxide.

(17) Myrophine.

(18) Nicocodeine.

(19) Nicomorphine.

(20) Normorphine.

(21) Pholcodine.

(22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 3,4-methylenedioxy amphetamine.

(2) 5-methoxy-3,4-methylenedioxy amphetamine.

(3) 3,4,5-trimethoxy amphetamine.

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(4) Bufotenine.

(5) Diethyltryptamine.

(6) Dimethyltryptamine.

(7) 4-methyl-2,5-dimethoxyamphetamine.

(8) Ibogaine.

(9) Lysergic acid diethylamide.

(10) Marihuana.

(11) Mescaline.

(12) Peyote.

(13) N-ethyl-3-piperidyl benzilate.

(14) N-methyl-3-piperidyl benzilate.

(15) Psilocybin.

(16) Psilocyn.

(17) Tetrahydrocannabinols.

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(18) 4-methylmethcathinone (Mephedrone).

(19) 3,4-methylenedioxypyrovalerone (MDPV).

(20) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E).

(21) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D).

(22) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C).

(23) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I).

(24) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2).

(25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4).

(26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H).

(27) 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N).

(28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P).

(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

§ 812. Schedules of controlled substances, 21 USCA § 812

(2) In paragraph (1):

(A) The term “cannabimimetic agents” means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

(ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

(iv) 1-(1-naphthylmethylene)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.

(B) Such term includes--

(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497);

(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog);

(iii) 1-pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678);

(iv) 1-butyl-3-(1-naphthoyl)indole (JWH-073);

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- (v) 1-hexyl-3-(1-naphthoyl)indole (JWH-019);
- (vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);
- (vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);
- (viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081);
- (ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);
- (x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);
- (xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);
- (xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);
- (xiii) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19 and RCS-4);
- (xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8); and
- (xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).

Schedule II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

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(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) coca³ leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Alphaprodine.

(2) Anileridine.

(3) Bezitramide.

(4) Dihydrocodeine.

(5) Diphenoxylate.

(6) Fentanyl.

(7) Isomethadone.

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(8) Levomethorphan.

(9) Levorphanol.

(10) Metazocine.

(11) Methadone.

(12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.

(13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(14) Pethidine.

(15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

(18) Phenazocine.

(19) Piminodine.

(20) Racemethorphan.

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§ 812. Schedules of controlled substances, 21 USCA § 812

(21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

Schedule III

(a) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Phenmetrazine and its salts.

(3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

(4) Methylphenidate.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.

(2) Chorexadol.

(3) Glutethimide.

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(4) Lysergic acid.

(5) Lysergic acid amide.

(6) Methyprylon.

(7) Phencyclidine.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

(c) Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit,

§ 812. Schedules of controlled substances, 21 USCA § 812

with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(e) Anabolic steroids.

Schedule IV

(1) Barbital.

(2) Chloral betaine.

(3) Chloral hydrate.

(4) Ethchlorvynol.

(5) Ethinamate.

(6) Methohexital.

§ 812. Schedules of controlled substances, 21 USCA § 812

(7) Meprobamate.

(8) Methylphenobarbital.

(9) Paraldehyde.

(10) Petrichloral.

(11) Phenobarbital.

Schedule V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

CREDIT(S)

(Pub.L. 91-513, Title II, § 202, Oct. 27, 1970, 84 Stat. 1247; Pub.L. 95-633, Title I, § 103, Nov. 10, 1978, 92 Stat. 3772; Pub.L. 98-473, Title II, §§ 507(c), 509(b), Oct. 12, 1984, 98 Stat. 2071, 2072; Pub.L. 99-570, Title I, § 1867, Oct. 27, 1986, 100 Stat. 3207-55; Pub.L. 99-646, § 84, Nov. 10, 1986, 100 Stat. 3619; Pub.L. 101-647, Title XIX, § 1902(a), Nov. 29, 1990, 104 Stat. 4851; Pub.L. 112-144, Title XI, § 1152, July 9, 2012, 126 Stat. 1130.)

§ 812. Schedules of controlled substances, 21 USCA § 812

Footnotes

¹

Revised schedules are published in the Code of Federal Regulations, Part 1308 of Title 21, Food and Drugs.

²

So in original. Probably should be “Alphacetylmethadol”.

³

So in original. Probably should be capitalized.

21 U.S.C.A. § 812, 21 USCA § 812

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§ 821. Rules and regulations, 21 USCA § 821

United States Code Annotated

Title 21. Food and Drugs (Refs & Annos)

Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)

Subchapter I. Control and Enforcement

Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

21 U.S.C.A. § 821

§ 821. Rules and regulations

Effective: December 8, 2004

Currentness

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.

CREDIT(S)

(Pub.L. 91-513, Title II, § 301, Oct. 27, 1970, 84 Stat. 1253; [Pub.L. 103-200](#), § 3(a), Dec. 17, 1993, 107 Stat. 2336; [Pub.L. 108-447](#), Div. B, Title VI, § 633(b), Dec. 8, 2004, 118 Stat. 2922.)

21 U.S.C.A. § 821, 21 USCA § 821

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§ 822. Persons required to register, 21 USCA § 822

United States Code Annotated

Title 21. Food and Drugs (Refs & Annos)

Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)

Subchapter I. Control and Enforcement

Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

21 U.S.C.A. § 822

§ 822. Persons required to register

Effective: August 1, 2014

Currentness

(a) Period of registration

(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

(b) Authorized activities

Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

(c) Exceptions

The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this subchapter:

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(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in [section 802\(25\)](#) of this title.

(d) Waiver

The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e) Separate registration

(1) A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(2) Notwithstanding paragraph (1), a registrant who is a veterinarian shall not be required to have a separate registration in order to transport and dispense controlled substances in the usual course of veterinary practice at a site other than the registrant's registered principal place of business or professional practice, so long as the site of transporting and dispensing is located in a State where the veterinarian is licensed to practice veterinary medicine and is not a principal place of business or professional practice.

(f) Inspection

The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

(g)(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this subchapter may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if

§ 822. Persons required to register, 21 USCA § 822

(A) the person receiving the controlled substance is authorized under this subchapter to engage in such activity; and

(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

(2) In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

(3) The Attorney General may, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

(4) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.

CREDIT(S)

(Pub.L. 91-513, Title II, § 302, Oct. 27, 1970, 84 Stat. 1253; Pub.L. 98-473, Title II, § 510, Oct. 12, 1984, 98 Stat. 2072; Pub.L. 103-200, § 3(b), Dec. 17, 1993, 107 Stat. 2336; Pub.L. 111-273, § 3(a), Oct. 12, 2010, 124 Stat. 2859; Pub.L. 113-143, § 2, Aug. 1, 2014, 128 Stat. 1750.)

21 U.S.C.A. § 822, 21 USCA § 822

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§ 823. Registration requirements, 21 USCA § 823



KeyCite Yellow Flag - Negative Treatment

Proposed Legislation

[United States Code Annotated](#)[Title 21. Food and Drugs \(Refs & Annos\)](#)[Chapter 13. Drug Abuse Prevention and Control \(Refs & Annos\)](#)[Subchapter I. Control and Enforcement](#)[Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances](#)

21 U.S.C.A. § 823

§ 823. Registration requirements

Effective: April 15, 2009

[Currentness](#)

(a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;
- (2) compliance with applicable State and local law;
- (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
- (4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

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(5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

(6) such other factors as may be relevant to and consistent with the public health and safety.

(b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

(2) compliance with applicable State and local law;

(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to [section 826](#) of this title.

(d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he

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determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;
 - (2) compliance with applicable State and local law;
 - (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
 - (4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
 - (5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and
 - (6) such other factors as may be relevant to and consistent with the public health and safety.
- (e) Distributors of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
- (2) compliance with applicable State and local law;
- (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

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(4) past experience in the distribution of controlled substances; and

(5) such other factors as may be relevant to and consistent with the public health and safety.

(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V, and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in [section 824\(a\)](#) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional

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restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver

(1) Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

(A) if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

(B) if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with [section 827](#) of this title) on such drugs; and

(C) if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

(2)(A) Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

(B) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

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(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

(iii) The total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The Secretary may by regulation change such total number.

(C) For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

(i) The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] or section 262 of Title 42, been approved for use in maintenance or detoxification treatment.

(ii) The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

(I) The notification under subparagraph (B) is in writing and states the name of the practitioner.

(II) The notification identifies the registration issued for the practitioner pursuant to subsection (f) of this section.

(III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f) of this section.

(ii) Upon receiving a notification under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f) of this section. The identification number so assigned shall be appropriate to preserve the confidentiality of

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patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B). If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the physician an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of [section 824\(a\)\(4\)](#) of this title, consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) of this section to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

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- (i) The term “group practice” has the meaning given such term in [section 1395nn\(h\)\(4\) of Title 42](#).
- (ii) The term “qualifying physician” means a physician who is licensed under State law and who meets one or more of the following conditions:
- (I) The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.
- (II) The physician holds an addiction certification from the American Society of Addiction Medicine.
- (III) The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.
- (IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.
- (V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.
- (VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.
- (VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

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(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 120 days after October 17, 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science.

(I) During the 3-year period beginning on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs, to patients for maintenance or detoxification treatment in accordance with this paragraph unless, before the expiration of that 3-year period, the State enacts a law prohibiting a practitioner from dispensing such drugs or combinations of drug.¹

(J)(i) This paragraph takes effect on the date referred to in subparagraph (I), and remains in effect thereafter.

(ii) For purposes relating to clause (iii), the Secretary and the Attorney General may, during the 3-year period beginning on December 29, 2006, make determinations in accordance with the following:

(I) The Secretary may make a determination of whether treatments provided under waivers under subparagraph (A) have been effective forms of maintenance treatment and detoxification treatment in clinical settings; may make a determination of whether such waivers have significantly increased (relative to the beginning of such period) the availability of maintenance treatment and detoxification treatment; and may make a determination of whether such waivers have adverse consequences for the public health.

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(II) The Attorney General may make a determination of the extent to which there have been violations of the numerical limitations established under subparagraph (B) for the number of individuals to whom a practitioner may provide treatment; may make a determination of whether waivers under subparagraph (A) have increased (relative to the beginning of such period) the extent to which narcotic drugs in schedule III, IV, or V or combinations of such drugs are being dispensed or possessed in violation of this chapter; and may make a determination of whether such waivers have adverse consequences for the public health.

(iii) If, before the expiration of the period specified in clause (ii), the Secretary or the Attorney General publishes in the Federal Register a decision, made on the basis of determinations under such clause, that subparagraph (B)(iii) should be applied by limiting the total number of patients a practitioner may treat to 30, then the provisions in such subparagraph (B)(iii) permitting more than 30 patients shall not apply, effective 60 days after the date on which the decision is so published. The Secretary shall in making any such decision consult with the Attorney General, and shall in publishing the decision in the Federal Register include any comments received from the Attorney General for inclusion in the publication. The Attorney General shall in making any such decision consult with the Secretary, and shall in publishing the decision in the Federal Register include any comments received from the Secretary for inclusion in the publication.

(h) Applicants for distribution of list I chemicals

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of [section 802\(39\)\(A\)](#) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider--

- (1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;
- (2) compliance by the applicant with applicable Federal, State, and local law;
- (3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;
- (4) any past experience of the applicant in the manufacture and distribution of chemicals; and
- (5) such other factors as are relevant to and consistent with the public health and safety.

§ 823. Registration requirements, 21 USCA § 823

CREDIT(S)

(Pub.L. 91-513, Title II, § 303, Oct. 27, 1970, 84 Stat. 1253; Pub.L. 93-281, § 3, May 14, 1974, 88 Stat. 124; Pub.L. 95-633, Title I, § 109, Nov. 10, 1978, 92 Stat. 3773; Pub.L. 98-473, Title II, § 511, Oct. 12, 1984, 98 Stat. 2073; Pub.L. 103-200, § 3(c), Dec. 17, 1993, 107 Stat. 2336; Pub.L. 106-310, Div. B, Title XXXV, § 3502(a), Oct. 17, 2000, 114 Stat. 1222; Pub.L. 107-273, Div. B, Title II, § 2501, Nov. 2, 2002, 116 Stat. 1803; Pub.L. 109-56, § 1(a), (b), Aug. 2, 2005, 119 Stat. 591; Pub.L. 109-177, Title VII, § 712(a)(3), Mar. 9, 2006, 120 Stat. 263; Pub.L. 109-469, Title XI, § 1102, Dec. 29, 2006, 120 Stat. 3540; Pub.L. 110-425, § 3(b), Oct. 15, 2008, 122 Stat. 4824.)

Footnotes

¹

So in original. Probably should be “drugs”.

21 U.S.C.A. § 823, 21 USCA § 823

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§ 825. Labeling and packaging, 21 USCA § 825

United States Code Annotated**Title 21. Food and Drugs (Refs & Annos)****Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)****Subchapter I. Control and Enforcement****Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances****21 U.S.C.A. § 825****§ 825. Labeling and packaging****Effective: December 18, 2014**

Currentness

(a) Symbol

It shall be unlawful to distribute a controlled substance in a commercial container unless such container, when and as required by regulations of the Attorney General, bears a label (as defined in [section 321\(k\)](#) of this title) containing an identifying symbol for such substance in accordance with such regulations. A different symbol shall be required for each schedule of controlled substances.

(b) Unlawful distribution without identifying symbol

It shall be unlawful for the manufacturer of any controlled substance to distribute such substance unless the labeling (as defined in [section 321\(m\)](#) of this title) of such substance contains, when and as required by regulations of the Attorney General, the identifying symbol required under subsection (a) of this section.

(c) Warning on label

The Secretary shall prescribe regulations under [section 353\(b\)](#) of this title which shall provide that the label of a drug listed in schedule II, III, or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient.

(d) Containers to be securely sealed

It shall be unlawful to distribute controlled substances in schedule I or II, and narcotic drugs in schedule III or IV, unless the bottle or other container, stopper, covering, or wrapper thereof is securely sealed as required by regulations of the Attorney

§ 825. Labeling and packaging, 21 USCA § 825

General.

(e) False labeling of anabolic steroids

(1) It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, an anabolic steroid or product containing an anabolic steroid, unless the steroid or product bears a label clearly identifying an anabolic steroid or product containing an anabolic steroid by the nomenclature used by the International Union of Pure and Applied Chemistry (IUPAC).

(2)(A) A product described in subparagraph (B) is exempt from the International Union of Pure and Applied Chemistry nomenclature requirement of this subsection if such product is labeled in the manner required under the Federal Food, Drug, and Cosmetic Act.

(B) A product is described in this subparagraph if the product--

(i) is the subject of an approved application as described in [section 355\(b\)](#) or [\(j\)](#) of this title; or

(ii) is exempt from the provisions of [section 355](#) of this title relating to new drugs because--

(I) it is intended solely for investigational use as described in [section 355\(i\)](#) of this title; and

(II) such product is being used exclusively for purposes of a clinical trial that is the subject of an effective investigational new drug application.

CREDIT(S)

(Pub.L. 91-513, Title II, § 305, Oct. 27, 1970, 84 Stat. 1256; [Pub.L. 113-260](#), § 3(a), Dec. 18, 2014, 128 Stat. 2931.)

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§ 827. Records and reports of registrants, 21 USCA § 827

United States Code Annotated**Title 21. Food and Drugs (Refs & Annos)****Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)****Subchapter I. Control and Enforcement****Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances****21 U.S.C.A. § 827****§ 827. Records and reports of registrants****Effective: April 15, 2009**

Currentness

(a) Inventory

Except as provided in subsection (c) of this section--

(1) every registrant under this subchapter shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant's regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;

(2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this subchapter manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

(3) on and after May 1, 1971, every registrant under this subchapter manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) Availability of records

Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant

§ 827. Records and reports of registrants, 21 USCA § 827

information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

(c) Nonapplicability

The foregoing provisions of this section shall not apply--

(1)(A) to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual; or

(B) to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of maintenance treatment or detoxification treatment of an individual;

(2)(A) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in research conducted in conformity with an exemption granted under [section 355\(i\)](#) or [360b\(j\)](#) of this title;

(B) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in preclinical research or in teaching; or

(3) to the extent of any exemption granted to any person, with respect to all or part of such provisions, by the Attorney General by or pursuant to regulation on the basis of a finding that the application of such provisions (or part thereof) to such person is not necessary for carrying out the purposes of this subchapter.

Nothing in the Convention on Psychotropic Substances shall be construed as superseding or otherwise affecting the provisions of paragraph (1)(B), (2), or (3) of this subsection.

(d)(1) Every manufacturer registered under [section 823](#) of this title shall, at such time or times and in such form as the

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Attorney General may require, make periodic reports to the Attorney General of every sale, delivery or other disposal by him of any controlled substance, and each distributor shall make such reports with respect to narcotic controlled substances, identifying by the registration number assigned under this subchapter the person or establishment (unless exempt from registration under [section 822\(d\)](#) of this title) to whom such sale, delivery, or other disposal was made.

(2) Each pharmacy with a modified registration under [section 823\(f\)](#) of this title that authorizes the dispensing of controlled substances by means of the Internet shall report to the Attorney General the controlled substances it dispenses, in the amount specified, and in such time and manner as the Attorney General by regulation shall require, except that the Attorney General, under this paragraph, may not require any pharmacy to report any information other than the total quantity of each controlled substance that the pharmacy has dispensed each month. For purposes of this paragraph, no reporting shall be required unless the pharmacy has met 1 of the following thresholds in the month for which the reporting is required:

(A) 100 or more prescriptions dispensed.

(B) 5,000 or more dosage units of all controlled substances combined.

(e) Reporting and recordkeeping requirements of drug conventions

In addition to the reporting and recordkeeping requirements under any other provision of this subchapter, each manufacturer registered under [section 823](#) of this title shall, with respect to narcotic and nonnarcotic controlled substances manufactured by it, make such reports to the Attorney General, and maintain such records, as the Attorney General may require to enable the United States to meet its obligations under articles 19 and 20 of the Single Convention on Narcotic Drugs and article 16 of the Convention on Psychotropic Substances. The Attorney General shall administer the requirements of this subsection in such a manner as to avoid the unnecessary imposition of duplicative requirements under this subchapter on manufacturers subject to the requirements of this subsection.

(f) Investigational uses of drugs; procedures

Regulations under [sections 355\(i\)](#) and [360\(j\)](#) of this title, relating to investigational use of drugs, shall include such procedures as the Secretary, after consultation with the Attorney General, determines are necessary to insure the security and accountability of controlled substances used in research to which such regulations apply.

(g) Change of address

Every registrant under this subchapter shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require.

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(h) Reporting requirements for GHB

In the case of a drug product containing gamma hydroxybutyric acid for which an application has been approved under [section 355](#) of this title, the Attorney General may, in addition to any other requirements that apply under this section with respect to such a drug product, establish any of the following as reporting requirements:

- (1) That every person who is registered as a manufacturer of bulk or dosage form, as a packager, repackager, labeler, relabeler, or distributor shall report acquisition and distribution transactions quarterly, not later than the 15th day of the month succeeding the quarter for which the report is submitted, and annually report end-of-year inventories.
- (2) That all annual inventory reports shall be filed no later than January 15 of the year following that for which the report is submitted and include data on the stocks of the drug product, drug substance, bulk drug, and dosage forms on hand as of the close of business December 31, indicating whether materials reported are in storage or in process of manufacturing.
- (3) That every person who is registered as a manufacturer of bulk or dosage form shall report all manufacturing transactions both inventory increases, including purchases, transfers, and returns, and reductions from inventory, including sales, transfers, theft, destruction, and seizure, and shall provide data on material manufactured, manufactured from other material, use in manufacturing other material, and use in manufacturing dosage forms.
- (4) That all reports under this section must include the registered person's registration number as well as the registration numbers, names, and other identifying information of vendors, suppliers, and customers, sufficient to allow the Attorney General to track the receipt and distribution of the drug.
- (5) That each dispensing practitioner shall maintain for each prescription the name of the prescribing practitioner, the prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations, verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance, the patient's name and address, the name of the patient's insurance provider and documentation by a medical practitioner licensed and registered to prescribe the drug of the patient's medical need for the drug. Such information shall be available for inspection and copying by the Attorney General.
- (6) That [section 830\(b\)\(3\)](#) of this title (relating to mail order reporting) applies with respect to gamma hydroxybutyric acid to the same extent and in the same manner as such section applies with respect to the chemicals and drug products specified in subparagraph (A)(i) of such section.

CREDIT(S)

ADD137

§ 827. Records and reports of registrants, 21 USCA § 827

(Pub.L. 91-513, Title II, § 307, Oct. 27, 1970, 84 Stat. 1258; Pub.L. 93-281, § 5, May 14, 1974, 88 Stat. 125; Pub.L. 95-633, Title I, §§ 104, 110, Nov. 10, 1978, 92 Stat. 3772, 3773; Pub.L. 98-473, Title II, §§ 514, 515, Oct. 12, 1984, 98 Stat. 2074; Pub.L. 106-172, § 4, Feb. 18, 2000, 114 Stat. 9; Pub.L. 110-425, § 3(c), Oct. 15, 2008, 122 Stat. 4824.)

21 U.S.C.A. § 827, 21 USCA § 827

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§ 829. Prescriptions, 21 USCA § 829

United States Code Annotated

Title 21. Food and Drugs (Refs & Annos)

Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)

Subchapter I. Control and Enforcement

Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

21 U.S.C.A. § 829

§ 829. Prescriptions

Effective: April 15, 2009

Currentness

(a) Schedule II substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], may be dispensed without the written prescription of a practitioner, except that in emergency situations, as prescribed by the Secretary by regulation after consultation with the Attorney General, such drug may be dispensed upon oral prescription in accordance with section 503(b) of that Act [21 U.S.C.A. § 353(b)]. Prescriptions shall be retained in conformity with the requirements of section 827 of this title. No prescription for a controlled substance in schedule II may be refilled.

(b) Schedule III and IV substances

Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.

(c) Schedule V substances

No controlled substance in schedule V which is a drug may be distributed or dispensed other than for a medical purpose.

(d) Non-prescription drugs with abuse potential

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Whenever it appears to the Attorney General that a drug not considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 *et seq.*] should be so considered because of its abuse potential, he shall so advise the Secretary and furnish to him all available data relevant thereto.

(e) Controlled substances dispensed by means of the Internet

(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

(2) As used in this subsection:

(A) The term “valid prescription” means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by--

(i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or

(ii) a covering practitioner.

(B)(i) The term “in-person medical evaluation” means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

(ii) Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(C) The term “covering practitioner” means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who--

(i) has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and

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(ii) is temporarily unavailable to conduct the evaluation of the patient.

(3) Nothing in this subsection shall apply to--

(A) the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine; or

(B) the dispensing or selling of a controlled substance pursuant to practices as determined by the Attorney General by regulation, which shall be consistent with effective controls against diversion.

CREDIT(S)

(Pub.L. 91-513, Title II, § 309, Oct. 27, 1970, 84 Stat. 1260; Pub.L. 110-425, § 2, Oct. 15, 2008, 122 Stat. 4820.)

21 U.S.C.A. § 829, 21 USCA § 829

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§ 841. Prohibited acts A, 21 USCA § 841



KeyCite Yellow Flag - Negative Treatment

Unconstitutional or Preempted **Prior Version Held Unconstitutional by U.S. v. Grant**, C.D.Cal., Nov. 30, 2007

KeyCite Yellow Flag - Negative Treatment Proposed Legislation

United States Code Annotated**Title 21. Food and Drugs (Refs & Annos)****Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)****Subchapter I. Control and Enforcement****Part D. Offenses and Penalties****21 U.S.C.A. § 841****§ 841. Prohibited acts A****Effective: August 3, 2010**[Currentness](#)**(a) Unlawful acts**

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally--

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance; or**(2)** to create, distribute, or dispense, or possess with intent to distribute or dispense, a counterfeit substance.**(b) Penalties**Except as otherwise provided in [section 849](#), [859](#), [860](#), or [861](#) of this title, any person who violates subsection (a) of this section shall be sentenced as follows:**(1)(A)** In the case of a violation of subsection (a) of this section involving--**(i)** 1 kilogram or more of a mixture or substance containing a detectable amount of heroin;

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(ii) 5 kilograms or more of a mixture or substance containing a detectable amount of--

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 280 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

(iv) 100 grams or more of phencyclidine (PCP) or 1 kilogram or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 10 grams or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 400 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidiny] propanamide or 100 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidiny] propanamide;

(vii) 1000 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 1,000 or more marihuana plants regardless of weight; or

(viii) 50 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 500 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

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such person shall be sentenced to a term of imprisonment which may not be less than 10 years or more than life and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of Title 18 or \$10,000,000 if the defendant is an individual or \$50,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment which may not be less than 20 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of Title 18 or \$20,000,000 if the defendant is an individual or \$75,000,000 if the defendant is other than an individual, or both. If any person commits a violation of this subparagraph or of [section 849](#), 859, 860, or 861 of this title after two or more prior convictions for a felony drug offense have become final, such person shall be sentenced to a mandatory term of life imprisonment without release and fined in accordance with the preceding sentence. Notwithstanding [section 3583 of Title 18](#), any sentence under this subparagraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 5 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 10 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

(B) In the case of a violation of subsection (a) of this section involving--

(i) 100 grams or more of a mixture or substance containing a detectable amount of heroin;

(ii) 500 grams or more of a mixture or substance containing a detectable amount of--

(I) coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed;

(II) cocaine, its salts, optical and geometric isomers, and salts of isomers;

(III) ecgonine, its derivatives, their salts, isomers, and salts of isomers; or

(IV) any compound, mixture, or preparation which contains any quantity of any of the substances referred to in subclauses (I) through (III);

(iii) 28 grams or more of a mixture or substance described in clause (ii) which contains cocaine base;

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(iv) 10 grams or more of phencyclidine (PCP) or 100 grams or more of a mixture or substance containing a detectable amount of phencyclidine (PCP);

(v) 1 gram or more of a mixture or substance containing a detectable amount of lysergic acid diethylamide (LSD);

(vi) 40 grams or more of a mixture or substance containing a detectable amount of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide or 10 grams or more of a mixture or substance containing a detectable amount of any analogue of N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl] propanamide;

(vii) 100 kilograms or more of a mixture or substance containing a detectable amount of marihuana, or 100 or more marihuana plants regardless of weight; or

(viii) 5 grams or more of methamphetamine, its salts, isomers, and salts of its isomers or 50 grams or more of a mixture or substance containing a detectable amount of methamphetamine, its salts, isomers, or salts of its isomers;

such person shall be sentenced to a term of imprisonment which may not be less than 5 years and not more than 40 years and if death or serious bodily injury results from the use of such substance shall be not less than 20 years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of Title 18 or \$5,000,000 if the defendant is an individual or \$25,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment which may not be less than 10 years and not more than life imprisonment and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions of Title 18 or \$8,000,000 if the defendant is an individual or \$50,000,000 if the defendant is other than an individual, or both. Notwithstanding [section 3583 of Title 18](#), any sentence imposed under this subparagraph shall, in the absence of such a prior conviction, include a term of supervised release of at least 4 years in addition to such term of imprisonment and shall, if there was such a prior conviction, include a term of supervised release of at least 8 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under this subparagraph. No person sentenced under this subparagraph shall be eligible for parole during the term of imprisonment imposed therein.

(C) In the case of a controlled substance in schedule I or II, gamma hydroxybutyric acid (including when scheduled as an approved drug product for purposes of section 3(a)(1)(B) of the Hillory J. Farias and Samantha Reid Date-Rape Drug Prohibition Act of 2000), or 1 gram of flunitrazepam, except as provided in subparagraphs (A), (B), and (D), such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not less than twenty years or more than life, a fine not to exceed the greater of that authorized in accordance with the provisions of Title 18 or \$1,000,000 if the defendant is an individual or \$5,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 30 years and if death or serious bodily injury results from the use of such substance shall be sentenced to life imprisonment, a fine not to exceed the greater of twice that authorized in accordance with the provisions

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of Title 18 or \$2,000,000 if the defendant is an individual or \$10,000,000 if the defendant is other than an individual, or both. Notwithstanding [section 3583 of Title 18](#), any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 3 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 6 years in addition to such term of imprisonment. Notwithstanding any other provision of law, the court shall not place on probation or suspend the sentence of any person sentenced under the provisions of this subparagraph which provide for a mandatory term of imprisonment if death or serious bodily injury results, nor shall a person so sentenced be eligible for parole during the term of such a sentence.

(D) In the case of less than 50 kilograms of marihuana, except in the case of 50 or more marihuana plants regardless of weight, 10 kilograms of hashish, or one kilogram of hashish oil, such person shall, except as provided in paragraphs (4) and (5) of this subsection, be sentenced to a term of imprisonment of not more than 5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of Title 18 or \$250,000 if the defendant is an individual or \$1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of Title 18 or \$500,000 if the defendant is an individual or \$2,000,000 if the defendant is other than an individual, or both. Notwithstanding [section 3583 of Title 18](#), any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 4 years in addition to such term of imprisonment.

(E)(i) Except as provided in subparagraphs (C) and (D), in the case of any controlled substance in schedule III, such person shall be sentenced to a term of imprisonment of not more than 10 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not more than 15 years, a fine not to exceed the greater of that authorized in accordance with the provisions of Title 18 or \$500,000 if the defendant is an individual or \$2,500,000 if the defendant is other than an individual, or both.

(ii) If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 20 years and if death or serious bodily injury results from the use of such substance shall be sentenced to a term of imprisonment of not more than 30 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of Title 18 or \$1,000,000 if the defendant is an individual or \$5,000,000 if the defendant is other than an individual, or both.

(iii) Any sentence imposing a term of imprisonment under this subparagraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 4 years in addition to such term of imprisonment.

(2) In the case of a controlled substance in schedule IV, such person shall be sentenced to a term of imprisonment of not more than 5 years, a fine not to exceed the greater of that authorized in accordance with the provisions of Title 18 or

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\$250,000 if the defendant is an individual or \$1,000,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 10 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of Title 18 or \$500,000 if the defendant is an individual or \$2,000,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph shall, in the absence of such a prior conviction, impose a term of supervised release of at least one year in addition to such term of imprisonment and shall, if there was such a prior conviction, impose a term of supervised release of at least 2 years in addition to such term of imprisonment.

(3) In the case of a controlled substance in schedule V, such person shall be sentenced to a term of imprisonment of not more than one year, a fine not to exceed the greater of that authorized in accordance with the provisions of Title 18 or \$100,000 if the defendant is an individual or \$250,000 if the defendant is other than an individual, or both. If any person commits such a violation after a prior conviction for a felony drug offense has become final, such person shall be sentenced to a term of imprisonment of not more than 4 years, a fine not to exceed the greater of twice that authorized in accordance with the provisions of Title 18 or \$200,000 if the defendant is an individual or \$500,000 if the defendant is other than an individual, or both. Any sentence imposing a term of imprisonment under this paragraph may, if there was a prior conviction, impose a term of supervised release of not more than 1 year, in addition to such term of imprisonment.

(4) Notwithstanding paragraph (1)(D) of this subsection, any person who violates subsection (a) of this section by distributing a small amount of marihuana for no remuneration shall be treated as provided in [section 844](#) of this title and [section 3607](#) of Title 18.

(5) Any person who violates subsection (a) of this section by cultivating or manufacturing a controlled substance on Federal property shall be imprisoned as provided in this subsection and shall be fined any amount not to exceed--

(A) the amount authorized in accordance with this section;

(B) the amount authorized in accordance with the provisions of Title 18;

(C) \$500,000 if the defendant is an individual; or

(D) \$1,000,000 if the defendant is other than an individual;

or both.

(6) Any person who violates subsection (a), or attempts to do so, and knowingly or intentionally uses a poison, chemical,

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or other hazardous substance on Federal land, and, by such use--

(A) creates a serious hazard to humans, wildlife, or domestic animals,

(B) degrades or harms the environment or natural resources, or

(C) pollutes an aquifer, spring, stream, river, or body of water,

shall be fined in accordance with Title 18 or imprisoned not more than five years, or both.

(7) Penalties for distribution

(A) In general

Whoever, with intent to commit a crime of violence, as defined in [section 16 of Title 18](#) (including rape), against an individual, violates subsection (a) of this section by distributing a controlled substance or controlled substance analogue to that individual without that individual's knowledge, shall be imprisoned not more than 20 years and fined in accordance with Title 18.

(B) Definition

For purposes of this paragraph, the term "without that individual's knowledge" means that the individual is unaware that a substance with the ability to alter that individual's ability to appraise conduct or to decline participation in or communicate unwillingness to participate in conduct is administered to the individual.

(c) Offenses involving listed chemicals

Any person who knowingly or intentionally--

(1) possesses a listed chemical with intent to manufacture a controlled substance except as authorized by this subchapter;

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(2) possesses or distributes a listed chemical knowing, or having reasonable cause to believe, that the listed chemical will be used to manufacture a controlled substance except as authorized by this subchapter; or

(3) with the intent of causing the evasion of the recordkeeping or reporting requirements of [section 830](#) of this title, or the regulations issued under that section, receives or distributes a reportable amount of any listed chemical in units small enough so that the making of records or filing of reports under that section is not required;

shall be fined in accordance with Title 18 or imprisoned not more than 20 years in the case of a violation of paragraph (1) or (2) involving a list I chemical or not more than 10 years in the case of a violation of this subsection other than a violation of paragraph (1) or (2) involving a list I chemical, or both.

(d) Boobytraps on Federal property; penalties; “boobytrap” defined

(1) Any person who assembles, maintains, places, or causes to be placed a boobytrap on Federal property where a controlled substance is being manufactured, distributed, or dispensed shall be sentenced to a term of imprisonment for not more than 10 years or fined under Title 18, or both.

(2) If any person commits such a violation after 1 or more prior convictions for an offense punishable under this subsection, such person shall be sentenced to a term of imprisonment of not more than 20 years or fined under Title 18, or both.

(3) For the purposes of this subsection, the term “boobytrap” means any concealed or camouflaged device designed to cause bodily injury when triggered by any action of any unsuspecting person making contact with the device. Such term includes guns, ammunition, or explosive devices attached to trip wires or other triggering mechanisms, sharpened stakes, and lines or wires with hooks attached.

(e) Ten-year injunction as additional penalty

In addition to any other applicable penalty, any person convicted of a felony violation of this section relating to the receipt, distribution, manufacture, exportation, or importation of a listed chemical may be enjoined from engaging in any transaction involving a listed chemical for not more than ten years.

(f) Wrongful distribution or possession of listed chemicals

(1) Whoever knowingly distributes a listed chemical in violation of this subchapter (other than in violation of a recordkeeping or reporting requirement of [section 830](#) of this title) shall, except to the extent that paragraph (12), (13), or (14) of [section](#)

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842(a) of this title applies, be fined under Title 18 or imprisoned not more than 5 years, or both.

(2) Whoever possesses any listed chemical, with knowledge that the recordkeeping or reporting requirements of [section 830](#) of this title have not been adhered to, if, after such knowledge is acquired, such person does not take immediate steps to remedy the violation shall be fined under Title 18 or imprisoned not more than one year, or both.

(g) Internet sales of date rape drugs

(1) Whoever knowingly uses the Internet to distribute a date rape drug to any person, knowing or with reasonable cause to believe that--

(A) the drug would be used in the commission of criminal sexual conduct; or

(B) the person is not an authorized purchaser;

shall be fined under this subchapter or imprisoned not more than 20 years, or both.

(2) As used in this subsection:

(A) The term “date rape drug” means--

(i) gamma hydroxybutyric acid (GHB) or any controlled substance analogue of GHB, including gamma butyrolactone (GBL) or 1,4-butanediol;

(ii) ketamine;

(iii) flunitrazepam; or

(iv) any substance which the Attorney General designates, pursuant to the rulemaking procedures prescribed by [section 553 of Title 5](#), to be used in committing rape or sexual assault.

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The Attorney General is authorized to remove any substance from the list of date rape drugs pursuant to the same rulemaking authority.

(B) The term “authorized purchaser” means any of the following persons, provided such person has acquired the controlled substance in accordance with this chapter:

(i) A person with a valid prescription that is issued for a legitimate medical purpose in the usual course of professional practice that is based upon a qualifying medical relationship by a practitioner registered by the Attorney General. A “qualifying medical relationship” means a medical relationship that exists when the practitioner has conducted at least 1 medical evaluation with the authorized purchaser in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals. The preceding sentence shall not be construed to imply that 1 medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

(ii) Any practitioner or other registrant who is otherwise authorized by their registration to dispense, procure, purchase, manufacture, transfer, distribute, import, or export the substance under this chapter.

(iii) A person or entity providing documentation that establishes the name, address, and business of the person or entity and which provides a legitimate purpose for using any “date rape drug” for which a prescription is not required.

(3) The Attorney General is authorized to promulgate regulations for record-keeping and reporting by persons handling 1,4-butanediol in order to implement and enforce the provisions of this section. Any record or report required by such regulations shall be considered a record or report required under this chapter.

(h) Offenses involving dispensing of controlled substances by means of the Internet

(1) In general

It shall be unlawful for any person to knowingly or intentionally--

(A) deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this subchapter; or

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(B) aid or abet (as such terms are used in [section 2 of Title 18](#)) any activity described in subparagraph (A) that is not authorized by this subchapter.

(2) Examples

Examples of activities that violate paragraph (1) include, but are not limited to, knowingly or intentionally--

(A) delivering, distributing, or dispensing a controlled substance by means of the Internet by an online pharmacy that is not validly registered with a modification authorizing such activity as required by [section 823\(f\)](#) of this title (unless exempt from such registration);

(B) writing a prescription for a controlled substance for the purpose of delivery, distribution, or dispensation by means of the Internet in violation of [section 829\(e\)](#) of this title;

(C) serving as an agent, intermediary, or other entity that causes the Internet to be used to bring together a buyer and seller to engage in the dispensing of a controlled substance in a manner not authorized by sections² [823\(f\)](#) or [829\(e\)](#) of this title;

(D) offering to fill a prescription for a controlled substance based solely on a consumer's completion of an online medical questionnaire; and

(E) making a material false, fictitious, or fraudulent statement or representation in a notification or declaration under subsection (d) or (e), respectively, of [section 831](#) of this title.

(3) Inapplicability

(A) This subsection does not apply to--

(i) the delivery, distribution, or dispensation of controlled substances by nonpractitioners to the extent authorized by their registration under this subchapter;

(ii) the placement on the Internet of material that merely advocates the use of a controlled substance or includes

§ 841. Prohibited acts A, 21 USCA § 841

pricing information without attempting to propose or facilitate an actual transaction involving a controlled substance;
or

(iii) except as provided in subparagraph (B), any activity that is limited to--

(I) the provision of a telecommunications service, or of an Internet access service or Internet information location tool (as those terms are defined in [section 231 of Title 47](#)); or

(II) the transmission, storage, retrieval, hosting, formatting, or translation (or any combination thereof) of a communication, without selection or alteration of the content of the communication, except that deletion of a particular communication or material made by another person in a manner consistent with [section 230\(c\) of Title 47](#) shall not constitute such selection or alteration of the content of the communication.

(B) The exceptions under subclauses (I) and (II) of subparagraph (A)(iii) shall not apply to a person acting in concert with a person who violates paragraph (1).

(4) Knowing or intentional violation

Any person who knowingly or intentionally violates this subsection shall be sentenced in accordance with subsection (b).

CREDIT(S)

(Pub.L. 91-513, Title II, § 401, Oct. 27, 1970, 84 Stat. 1260; [Pub.L. 95-633, Title II, § 201](#), Nov. 10, 1978, 92 Stat. 3774; [Pub.L. 96-359](#), § 8(c), Sept. 26, 1980, 94 Stat. 1194; [Pub.L. 98-473, Title II, §§ 224\(a\)](#), 502, 503(b)(1), (2), Oct. 12, 1984, 98 Stat. 2030, 2068, 2070; [Pub.L. 99-570, Title I, §§ 1002](#), 1003(a), 1004(a), 1005(a), 1103, Title XV, § 15005, Oct. 27, 1986, 100 Stat. 3207-2, 3207-5, 3207-6, 3207-11, 3207-192; [Pub.L. 100-690, Title VI, §§ 6055](#), 6254(h), 6452(a), 6470(g), (h), 6479, Nov. 18, 1988, 102 Stat. 4318, 4367, 4371, 4378, 4381; [Pub.L. 101-647, Title X, § 1002\(e\)](#), Title XII, § 1202, Title XXXV, § 3599K, Nov. 29, 1990, 104 Stat. 4828, 4830, 4932; [Pub.L. 103-322, Title IX, § 90105\(a\)](#), (c), Title XVIII, § 180201(b)(2)(A), Sept. 13, 1994, 108 Stat. 1987, 1988, 2047; [Pub.L. 104-237, Title II, § 206\(a\)](#), Title III, § 302(a), Oct. 3, 1996, 110 Stat. 3103, 3105; [Pub.L. 104-305](#), § 2(a), (b)(1), Oct. 13, 1996, 110 Stat. 3807; [Pub.L. 105-277](#), Div. E, § 2(a), Oct. 21, 1998, 112 Stat. 2681-759; [Pub.L. 106-172](#), §§ 3(b)(1), 5(b), 9, Feb. 18, 2000, 114 Stat. 9, 10, 13; [Pub.L. 107-273](#), Div. B, Title III, § 3005(a), Title IV, § 4002(d)(2)(A), Nov. 2, 2002, 116 Stat. 1805, 1809; [Pub.L. 109-177, Title VII, §§ 711\(f\)\(1\)\(B\)](#), 732, Mar. 9, 2006, 120 Stat. 262, 270; [Pub.L. 109-248, Title II, § 201](#), July 27, 2006, 120 Stat. 611; [Pub.L. 110-425](#), § 3(e), (f), Oct. 15, 2008, 122 Stat. 4828, 4829; [Pub.L. 111-220](#), §§ 2(a), 4(a), Aug. 3, 2010, 124 Stat. 2372.)

Footnotes

¹

So in original. Probably should be “health”.

ADD153

§ 841. Prohibited acts A, 21 USCA § 841

2

So in original. Probably should be "section".

21 U.S.C.A. § 841, 21 USCA § 841

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§ 842. Prohibited acts B, 21 USCA § 842



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Proposed Legislation

United States Code Annotated

Title 21. Food and Drugs (Refs & Annos)

Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)
--

Subchapter I. Control and Enforcement

Part D. Offenses and Penalties

21 U.S.C.A. § 842

§ 842. Prohibited acts B

Effective: December 18, 2014

[Currentness](#)

(a) Unlawful acts

It shall be unlawful for any person--

- (1) who is subject to the requirements of part C to distribute or dispense a controlled substance in violation of [section 829](#) of this title;
- (2) who is a registrant to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person or to manufacture a controlled substance not authorized by his registration;
- (3) who is a registrant to distribute a controlled substance in violation of [section 825](#) of this title;
- (4) to remove, alter, or obliterate a symbol or label required by [section 825](#) of this title;
- (5) to refuse or negligently fail to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under this subchapter or subchapter II of this chapter;
- (6) to refuse any entry into any premises or inspection authorized by this subchapter or subchapter II of this chapter;

§ 842. Prohibited acts B, 21 USCA § 842

(7) to remove, break, injure, or deface a seal placed upon controlled substances pursuant to [section 824\(f\)](#) or [881](#) of this title or to remove or dispose of substances so placed under seal;

(8) to use, to his own advantage, or to reveal, other than to duly authorized officers or employees of the United States, or to the courts when relevant in any judicial proceeding under this subchapter or subchapter II of this chapter, any information acquired in the course of an inspection authorized by this subchapter concerning any method or process which as a trade secret is entitled to protection, or to use to his own advantage or reveal (other than as authorized by [section 830](#) of this title) any information that is confidential under such section;

(9) who is a regulated person to engage in a regulated transaction without obtaining the identification required by [830\(a\)\(3\)](#) of this title.¹

(10) negligently to fail to keep a record or make a report under [section 830](#) of this title or negligently to fail to self-certify as required under [section 830](#) of this title;

(11) to distribute a laboratory supply to a person who uses, or attempts to use, that laboratory supply to manufacture a controlled substance or a listed chemical, in violation of this subchapter or subchapter II of this chapter, with reckless disregard for the illegal uses to which such a laboratory supply will be put;

(12) who is a regulated seller, or a distributor required to submit reports under [subsection \(b\)\(3\) of section 830](#) of this title--

(A) to sell at retail a scheduled listed chemical product in violation of paragraph (1) of subsection (d) of such section, knowing at the time of the transaction involved (independent of consulting the logbook under subsection (e)(1)(A)(iii) of such section) that the transaction is a violation; or

(B) to knowingly or recklessly sell at retail such a product in violation of paragraph (2) of such subsection (d);

(13) who is a regulated seller to knowingly or recklessly sell at retail a scheduled listed chemical product in violation of subsection (e) of such section;

(14) who is a regulated seller or an employee or agent of such seller to disclose, in violation of regulations under [subparagraph \(C\) of section 830\(e\)\(1\)](#) of this title, information in logbooks under subparagraph (A)(iii) of such section, or

§ 842. Prohibited acts B, 21 USCA § 842

to refuse to provide such a logbook to Federal, State, or local law enforcement authorities;

(15) to distribute a scheduled listed chemical product to a regulated seller, or to a regulated person referred to in [section 830\(b\)\(3\)\(B\)](#) of this title, unless such regulated seller or regulated person is, at the time of such distribution, currently registered with the Drug Enforcement Administration, or on the list of persons referred to under [section 830\(e\)\(1\)\(B\)\(v\)](#) of this title; or

(16) to violate [subsection \(e\) of section 825](#) of this title.

As used in paragraph (11), the term “laboratory supply” means a listed chemical or any chemical, substance, or item on a special surveillance list published by the Attorney General, which contains chemicals, products, materials, or equipment used in the manufacture of controlled substances and listed chemicals. For purposes of paragraph (11), there is a rebuttable presumption of reckless disregard at trial if the Attorney General notifies a firm in writing that a laboratory supply sold by the firm, or any other person or firm, has been used by a customer of the notified firm, or distributed further by that customer, for the unlawful production of controlled substances or listed chemicals a firm distributes and 2 weeks or more after the notification the notified firm distributes a laboratory supply to the customer. For purposes of paragraph (15), if the distributor is temporarily unable to access the list of persons referred to under [section 830\(e\)\(1\)\(B\)\(v\)](#) of this title, the distributor may rely on a written, faxed, or electronic copy of a certificate of self-certification submitted by the regulated seller or regulated person, provided the distributor confirms within 7 business days of the distribution that such regulated seller or regulated person is on the list referred to under [section 830\(e\)\(1\)\(B\)\(v\)](#) of this title.

(b) Manufacture

It shall be unlawful for any person who is a registrant to manufacture a controlled substance in schedule I or II, or ephedrine, pseudoephedrine, or phenylpropanolamine or any of the salts, optical isomers, or salts of optical isomers of such chemical, which is--

(1) not expressly authorized by his registration and by a quota assigned to him pursuant to [section 826](#) of this title; or

(2) in excess of a quota assigned to him pursuant to [section 826](#) of this title.

(c) Penalties

(1)(A) Except as provided in subparagraph (B), (C), or (D) of this paragraph and paragraph (2), any person who violates this section shall, with respect to any such violation, be subject to a civil penalty of not more than \$25,000. The district courts of the United States (or, where there is no such court in the case of any territory or possession of the United States, then the

§ 842. Prohibited acts B, 21 USCA § 842

court in such territory or possession having the jurisdiction of a district court of the United States in cases arising under the Constitution and laws of the United States) shall have jurisdiction in accordance with [section 1355 of Title 28](#) to enforce this paragraph.

(B) In the case of a violation of paragraph (5) or (10) of subsection (a) of this section, the civil penalty shall not exceed \$10,000.

(C) In the case of a violation of paragraph (16) of subsection (a) of this section by an importer, exporter, manufacturer, or distributor (other than as provided in subparagraph (D)), up to \$500,000 per violation. For purposes of this subparagraph, a “violation” is defined as each instance of importation, exportation, manufacturing, distribution, or possession with intent to manufacture or distribute, in violation of paragraph (16) of subsection (a).

(D) In the case of a distribution, dispensing, or possession with intent to distribute or dispense in violation of paragraph (16) of subsection (a) of this section at the retail level, up to \$1000 per violation. For purposes of this paragraph, the term “at the retail level” refers to products sold, or held for sale, directly to the consumer for personal use. Each package, container or other separate unit containing an anabolic steroid that is distributed, dispensed, or possessed with intent to distribute or dispense at the retail level in violation of such paragraph (16) of subsection (a) shall be considered a separate violation.

(2)(A) If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall, except as otherwise provided in subparagraph (B) of this paragraph, be sentenced to imprisonment of not more than one year or a fine under Title 18, or both.

(B) If a violation referred to in subparagraph (A) was committed after one or more prior convictions of the offender for an offense punishable under this paragraph (2), or for a crime under any other provision of this subchapter or subchapter II of this chapter or other law of the United States relating to narcotic drugs, marihuana, or depressant or stimulant substances, have become final, such person shall be sentenced to a term of imprisonment of not more than 2 years, a fine under Title 18, or both.

(C) In addition to the penalties set forth elsewhere in this subchapter or subchapter II of this chapter, any business that violates paragraph (11) of subsection (a) of this section shall, with respect to the first such violation, be subject to a civil penalty of not more than \$250,000, but shall not be subject to criminal penalties under this section, and shall, for any succeeding violation, be subject to a civil fine of not more than \$250,000 or double the last previously imposed penalty, whichever is greater.

(3) Except under the conditions specified in paragraph (2) of this subsection, a violation of this section does not constitute a crime, and a judgment for the United States and imposition of a civil penalty pursuant to paragraph (1) shall not give rise to any disability or legal disadvantage based on conviction for a criminal offense.

§ 842. Prohibited acts B, 21 USCA § 842

(4)(A) If a regulated seller, or a distributor required to submit reports under [section 830\(b\)\(3\)](#) of this title, violates paragraph (12) of subsection (a) of this section, or if a regulated seller violates paragraph (13) of such subsection, the Attorney General may by order prohibit such seller or distributor (as the case may be) from selling any scheduled listed chemical product. Any sale of such a product in violation of such an order is subject to the same penalties as apply under paragraph (2).

(B) An order under subparagraph (A) may be imposed only through the same procedures as apply under [section 824\(c\)](#) of this title for an order to show cause.

CREDIT(S)

(Pub.L. 91-513, Title II, § 402, Oct. 27, 1970, 84 Stat. 1262; [Pub.L. 95-633, Title II, § 202\(b\)\(1\), \(2\)](#), Nov. 10, 1978, 92 Stat. 3776; [Pub.L. 100-690, Title VI, § 6056](#), Nov. 18, 1988, 102 Stat. 4318; [Pub.L. 104-237, Title II, § 205](#), Oct. 3, 1996, 110 Stat. 3103; [Pub.L. 105-277, Div. A, § 101\(b\)](#) [Title I, § 117], Oct. 21, 1998, 112 Stat. 2681-68; [Pub.L. 107-273, Div. B, Title IV, § 4002\(b\)\(16\), \(d\)\(2\)\(B\)](#), Nov. 2, 2002, 116 Stat. 1808, 1809; [Pub.L. 109-177, Title VII, §§ 711\(f\)\(1\)\(A\), \(2\)](#), 714, Mar. 9, 2006, 120 Stat. 262 to 264; [Pub.L. 111-268, §§ 4, 5](#), Oct. 12, 2010, 124 Stat. 2847, 2848; [Pub.L. 113-260, § 3\(c\)](#), Dec. 18, 2014, 128 Stat. 2931.)

Footnotes

1

So in original. Probably should be “[section 830\(a\)\(3\)](#) of this title;”.

21 U.S.C.A. § 842, 21 USCA § 842

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§ 844. Penalties for simple possession, 21 USCA § 844

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated

Title 21. Food and Drugs (Refs & Annos)

Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)

Subchapter I. Control and Enforcement

Part D. Offenses and Penalties

21 U.S.C.A. § 844

§ 844. Penalties for simple possession

Effective: August 3, 2010

Currentness

(a) Unlawful acts; penalties

It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter or subchapter II of this chapter. It shall be unlawful for any person knowingly or intentionally to possess any list I chemical obtained pursuant to or under authority of a registration issued to that person under [section 823](#) of this title or [section 958](#) of this title if that registration has been revoked or suspended, if that registration has expired, or if the registrant has ceased to do business in the manner contemplated by his registration. It shall be unlawful for any person to knowingly or intentionally purchase at retail during a 30 day period more than 9 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a scheduled listed chemical product, except that, of such 9 grams, not more than 7.5 grams may be imported by means of shipping through any private or commercial carrier or the Postal Service. Any person who violates this subsection may be sentenced to a term of imprisonment of not more than 1 year, and shall be fined a minimum of \$1,000, or both, except that if he commits such offense after a prior conviction under this subchapter or subchapter II of this chapter, or a prior conviction for any drug, narcotic, or chemical offense chargeable under the law of any State, has become final, he shall be sentenced to a term of imprisonment for not less than 15 days but not more than 2 years, and shall be fined a minimum of \$2,500, except, further, that if he commits such offense after two or more prior convictions under this subchapter or subchapter II of this chapter, or two or more prior convictions for any drug, narcotic, or chemical offense chargeable under the law of any State, or a combination of two or more such offenses have become final, he shall be sentenced to a term of imprisonment for not less than 90 days but not more than 3 years, and shall be fined a minimum of \$5,000. Notwithstanding any penalty provided in this subsection, any person convicted under this subsection for the possession of flunitrazepam shall be imprisoned for not more than 3 years, shall be fined as otherwise provided in this section, or both. The imposition or execution of a minimum sentence required to be imposed under this subsection shall not be suspended or deferred. Further, upon conviction, a person who violates this subsection shall be fined the reasonable costs of the investigation and prosecution of the offense, including the costs of prosecution of an offense as defined in [sections 1918](#) and [1920 of Title 28](#), except that this sentence shall not apply and a fine under this section need not be imposed if the court determines under the provision of Title 18 that the defendant lacks the ability to pay.

§ 844. Penalties for simple possession, 21 USCA § 844

(b) Repealed. Pub.L. 98-473, Title II, § 219(a), Oct. 12, 1984, 98 Stat. 2027

(c) “Drug, narcotic, or chemical offense” defined

As used in this section, the term “drug, narcotic, or chemical offense” means any offense which proscribes the possession, distribution, manufacture, cultivation, sale, transfer, or the attempt or conspiracy to possess, distribute, manufacture, cultivate, sell or transfer any substance the possession of which is prohibited under this subchapter.

CREDIT(S)

(Pub.L. 91-513, Title II, § 404, Oct. 27, 1970, 84 Stat. 1264; Pub.L. 98-473, Title II, § 219, Oct. 12, 1984, 98 Stat. 2027; Pub.L. 99-570, Title I, § 1052, Oct. 27, 1986, 100 Stat. 3207-8; Pub.L. 100-690, Title VI, §§ 6371, 6480, Nov. 18, 1988, 102 Stat. 4370, 4382; Pub.L. 101-647, Title XII, § 1201, Title XIX, § 1907, Nov. 29, 1990, 104 Stat. 4829, 4854; Pub.L. 104-237, Title II, § 201(a), Oct. 3, 1996, 110 Stat. 3101; Pub.L. 104-305, § 2(c), Oct. 13, 1996, 110 Stat. 3808; Pub.L. 109-177, Title VII, § 711(e)(1), Mar. 9, 2006, 120 Stat. 262; Pub.L. 111-220, § 3, Aug. 3, 2010, 124 Stat. 2372.)

21 U.S.C.A. § 844, 21 USCA § 844

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§ 846. Attempt and conspiracy, 21 USCA § 846

United States Code Annotated**Title 21. Food and Drugs (Refs & Annos)****Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)****Subchapter I. Control and Enforcement****Part D. Offenses and Penalties****21 U.S.C.A. § 846****§ 846. Attempt and conspiracy**

Currentness

Any person who attempts or conspires to commit any offense defined in this subchapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

CREDIT(S)

(Pub.L. 91-513, Title II, § 406, Oct. 27, 1970, 84 Stat. 1265; Pub.L. 100-690, Title VI, § 6470(a), Nov. 18, 1988, 102 Stat. 4377.)

21 U.S.C.A. § 846, 21 USCA § 846

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§ 856. Maintaining drug-involved premises, 21 USCA § 856

United States Code Annotated

Title 21. Food and Drugs (Refs & Annos)

Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)

Subchapter I. Control and Enforcement

Part D. Offenses and Penalties

21 U.S.C.A. § 856

§ 856. Maintaining drug-involved premises

Effective: April 30, 2003

Currentness

(a) Unlawful acts

Except as authorized by this subchapter, it shall be unlawful to--

(1) knowingly open, lease, rent, use, or maintain any place, whether permanently or temporarily, for the purpose of manufacturing, distributing, or using any controlled substance;

(2) manage or control any place, whether permanently or temporarily, either as an owner, lessee, agent, employee, occupant, or mortgagee, and knowingly and intentionally rent, lease, profit from, or make available for use, with or without compensation, the place for the purpose of unlawfully manufacturing, storing, distributing, or using a controlled substance.

(b) Criminal penalties

Any person who violates subsection (a) of this section shall be sentenced to a term of imprisonment of not more than 20 years or a fine of not more than \$500,000, or both, or a fine of \$2,000,000 for a person other than an individual.

(c) Violation as offense against property

A violation of subsection (a) of this section shall be considered an offense against property for purposes of [section 3663A\(c\)\(1\)\(A\)\(ii\) of Title 18](#).

§ 856. Maintaining drug-involved premises, 21 USCA § 856

(d) Civil penalties

(1) Any person who violates subsection (a) of this section shall be subject to a civil penalty of not more than the greater of

(A) \$250,000; or

(B) 2 times the gross receipts, either known or estimated, that were derived from each violation that is attributable to the person.

(2) If a civil penalty is calculated under paragraph (1)(B), and there is more than 1 defendant, the court may apportion the penalty between multiple violators, but each violator shall be jointly and severally liable for the civil penalty under this subsection.

(e) Declaratory and injunctive remedies

Any person who violates subsection (a) of this section shall be subject to declaratory and injunctive remedies as set forth in [section 843\(f\)](#) of this title.

CREDIT(S)

(Pub.L. 91-513, Title II, § 416, as added [Pub.L. 99-570, Title I, § 1841\(a\)](#), Oct. 27, 1986, 100 Stat. 3207-52; amended [Pub.L. 106-310](#), Div. B, Title XXXVI, § 3613(e), Oct. 17, 2000, 114 Stat. 1230; [Pub.L. 108-21, Title VI, § 608\(b\)\(1\), \(2\), \(c\)](#), Apr. 30, 2003, 117 Stat. 691.)

21 U.S.C.A. § 856, 21 USCA § 856

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§ 1291. Final decisions of district courts, 28 USCA § 1291

United States Code Annotated**Title 28. Judiciary and Judicial Procedure (Refs & Annos)****Part IV. Jurisdiction and Venue (Refs & Annos)****Chapter 83. Courts of Appeals (Refs & Annos)****28 U.S.C.A. § 1291****§ 1291. Final decisions of district courts***Currentness*

The courts of appeals (other than the United States Court of Appeals for the Federal Circuit) shall have jurisdiction of appeals from all final decisions of the district courts of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam, and the District Court of the Virgin Islands, except where a direct review may be had in the Supreme Court. The jurisdiction of the United States Court of Appeals for the Federal Circuit shall be limited to the jurisdiction described in [sections 1292\(c\) and \(d\)](#) and [1295](#) of this title.

CREDIT(S)

(June 25, 1948, c. 646, 62 Stat. 929; Oct. 31, 1951, c. 655, § 48, 65 Stat. 726; July 7, 1958, Pub.L. 85-508, § 12(e), 72 Stat. 348; Apr. 2, 1982, [Pub.L. 97-164, Title I, § 124](#), 96 Stat. 36.)

28 U.S.C.A. § 1291, 28 USCA § 1291

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§ 1332. Diversity of citizenship; amount in controversy; costs, 28 USCA § 1332

United States Code Annotated

Title 28. Judiciary and Judicial Procedure (Refs & Annos)

Part IV. Jurisdiction and Venue (Refs & Annos)

Chapter 85. District Courts; Jurisdiction (Refs & Annos)

28 U.S.C.A. § 1332

§ 1332. Diversity of citizenship; amount in controversy; costs

Currentness

(a) The district courts shall have original jurisdiction of all civil actions where the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs, and is between--

(1) citizens of different States;

(2) citizens of a State and citizens or subjects of a foreign state, except that the district courts shall not have original jurisdiction under this subsection of an action between citizens of a State and citizens or subjects of a foreign state who are lawfully admitted for permanent residence in the United States and are domiciled in the same State;

(3) citizens of different States and in which citizens or subjects of a foreign state are additional parties; and

(4) a foreign state, defined in [section 1603\(a\)](#) of this title, as plaintiff and citizens of a State or of different States.

(b) Except when express provision therefor is otherwise made in a statute of the United States, where the plaintiff who files the case originally in the Federal courts is finally adjudged to be entitled to recover less than the sum or value of \$75,000, computed without regard to any setoff or counterclaim to which the defendant may be adjudged to be entitled, and exclusive of interest and costs, the district court may deny costs to the plaintiff and, in addition, may impose costs on the plaintiff.

(c) For the purposes of this section and [section 1441](#) of this title--

(1) a corporation shall be deemed to be a citizen of every State and foreign state by which it has been incorporated and of the State or foreign state where it has its principal place of business, except that in any direct action against the insurer of a policy or contract of liability insurance, whether incorporated or unincorporated, to which action the insured is not joined

§ 1332. Diversity of citizenship; amount in controversy; costs, 28 USCA § 1332

as a party-defendant, such insurer shall be deemed a citizen of--

(A) every State and foreign state of which the insured is a citizen;

(B) every State and foreign state by which the insurer has been incorporated; and

(C) the State or foreign state where the insurer has its principal place of business; and

(2) the legal representative of the estate of a decedent shall be deemed to be a citizen only of the same State as the decedent, and the legal representative of an infant or incompetent shall be deemed to be a citizen only of the same State as the infant or incompetent.

(d)(1) In this subsection--

(A) the term “class” means all of the class members in a class action;

(B) the term “class action” means any civil action filed under [rule 23 of the Federal Rules of Civil Procedure](#) or similar State statute or rule of judicial procedure authorizing an action to be brought by 1 or more representative persons as a class action;

(C) the term “class certification order” means an order issued by a court approving the treatment of some or all aspects of a civil action as a class action; and

(D) the term “class members” means the persons (named or unnamed) who fall within the definition of the proposed or certified class in a class action.

(2) The district courts shall have original jurisdiction of any civil action in which the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interest and costs, and is a class action in which--

(A) any member of a class of plaintiffs is a citizen of a State different from any defendant;

§ 1332. Diversity of citizenship; amount in controversy; costs, 28 USCA § 1332

(B) any member of a class of plaintiffs is a foreign state or a citizen or subject of a foreign state and any defendant is a citizen of a State; or

(C) any member of a class of plaintiffs is a citizen of a State and any defendant is a foreign state or a citizen or subject of a foreign state.

(3) A district court may, in the interests of justice and looking at the totality of the circumstances, decline to exercise jurisdiction under paragraph (2) over a class action in which greater than one-third but less than two-thirds of the members of all proposed plaintiff classes in the aggregate and the primary defendants are citizens of the State in which the action was originally filed based on consideration of--

(A) whether the claims asserted involve matters of national or interstate interest;

(B) whether the claims asserted will be governed by laws of the State in which the action was originally filed or by the laws of other States;

(C) whether the class action has been pleaded in a manner that seeks to avoid Federal jurisdiction;

(D) whether the action was brought in a forum with a distinct nexus with the class members, the alleged harm, or the defendants;

(E) whether the number of citizens of the State in which the action was originally filed in all proposed plaintiff classes in the aggregate is substantially larger than the number of citizens from any other State, and the citizenship of the other members of the proposed class is dispersed among a substantial number of States; and

(F) whether, during the 3-year period preceding the filing of that class action, 1 or more other class actions asserting the same or similar claims on behalf of the same or other persons have been filed.

(4) A district court shall decline to exercise jurisdiction under paragraph (2)--

§ 1332. Diversity of citizenship; amount in controversy; costs, 28 USCA § 1332

(A)(i) over a class action in which--

(I) greater than two-thirds of the members of all proposed plaintiff classes in the aggregate are citizens of the State in which the action was originally filed;

(II) at least 1 defendant is a defendant--

(aa) from whom significant relief is sought by members of the plaintiff class;

(bb) whose alleged conduct forms a significant basis for the claims asserted by the proposed plaintiff class; and

(cc) who is a citizen of the State in which the action was originally filed; and

(III) principal injuries resulting from the alleged conduct or any related conduct of each defendant were incurred in the State in which the action was originally filed; and

(ii) during the 3-year period preceding the filing of that class action, no other class action has been filed asserting the same or similar factual allegations against any of the defendants on behalf of the same or other persons; or

(B) two-thirds or more of the members of all proposed plaintiff classes in the aggregate, and the primary defendants, are citizens of the State in which the action was originally filed.

(5) Paragraphs (2) through (4) shall not apply to any class action in which--

(A) the primary defendants are States, State officials, or other governmental entities against whom the district court may be foreclosed from ordering relief; or

(B) the number of members of all proposed plaintiff classes in the aggregate is less than 100.

§ 1332. Diversity of citizenship; amount in controversy; costs, 28 USCA § 1332

(6) In any class action, the claims of the individual class members shall be aggregated to determine whether the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interest and costs.

(7) Citizenship of the members of the proposed plaintiff classes shall be determined for purposes of paragraphs (2) through (6) as of the date of filing of the complaint or amended complaint, or, if the case stated by the initial pleading is not subject to Federal jurisdiction, as of the date of service by plaintiffs of an amended pleading, motion, or other paper, indicating the existence of Federal jurisdiction.

(8) This subsection shall apply to any class action before or after the entry of a class certification order by the court with respect to that action.

(9) Paragraph (2) shall not apply to any class action that solely involves a claim--

(A) concerning a covered security as defined under 16(f)(3)¹ of the Securities Act of 1933 (15 U.S.C. 78p(f)(3)²) and section 28(f)(5)(E) of the Securities Exchange Act of 1934 (15 U.S.C. 78bb(f)(5)(E));

(B) that relates to the internal affairs or governance of a corporation or other form of business enterprise and that arises under or by virtue of the laws of the State in which such corporation or business enterprise is incorporated or organized; or

(C) that relates to the rights, duties (including fiduciary duties), and obligations relating to or created by or pursuant to any security (as defined under section 2(a)(1) of the Securities Act of 1933 (15 U.S.C. 77b(a)(1)) and the regulations issued thereunder).

(10) For purposes of this subsection and section 1453, an unincorporated association shall be deemed to be a citizen of the State where it has its principal place of business and the State under whose laws it is organized.

(11)(A) For purposes of this subsection and section 1453, a mass action shall be deemed to be a class action removable under paragraphs (2) through (10) if it otherwise meets the provisions of those paragraphs.

(B)(i) As used in subparagraph (A), the term “mass action” means any civil action (except a civil action within the scope of section 1711(2)) in which monetary relief claims of 100 or more persons are proposed to be tried jointly on the ground that the plaintiffs’ claims involve common questions of law or fact, except that jurisdiction shall exist only over those plaintiffs whose claims in a mass action satisfy the jurisdictional amount requirements under subsection (a).

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(ii) As used in subparagraph (A), the term “mass action” shall not include any civil action in which--

(I) all of the claims in the action arise from an event or occurrence in the State in which the action was filed, and that allegedly resulted in injuries in that State or in States contiguous to that State;

(II) the claims are joined upon motion of a defendant;

(III) all of the claims in the action are asserted on behalf of the general public (and not on behalf of individual claimants or members of a purported class) pursuant to a State statute specifically authorizing such action; or

(IV) the claims have been consolidated or coordinated solely for pretrial proceedings.

(C)(i) Any action(s) removed to Federal court pursuant to this subsection shall not thereafter be transferred to any other court pursuant to [section 1407](#), or the rules promulgated thereunder, unless a majority of the plaintiffs in the action request transfer pursuant to [section 1407](#).

(ii) This subparagraph will not apply--

(I) to cases certified pursuant to [rule 23 of the Federal Rules of Civil Procedure](#); or

(II) if plaintiffs propose that the action proceed as a class action pursuant to [rule 23 of the Federal Rules of Civil Procedure](#).

(D) The limitations periods on any claims asserted in a mass action that is removed to Federal court pursuant to this subsection shall be deemed tolled during the period that the action is pending in Federal court.

(e) The word “States”, as used in this section, includes the Territories, the District of Columbia, and the Commonwealth of Puerto Rico.

§ 1332. Diversity of citizenship; amount in controversy; costs, 28 USCA § 1332

CREDIT(S)

(June 25, 1948, c. 646, 62 Stat. 930; July 26, 1956, c. 740, 70 Stat. 658; July 25, 1958, Pub.L. 85-554, § 2, 72 Stat. 415; Aug. 14, 1964, Pub.L. 88-439, § 1, 78 Stat. 445; Oct. 21, 1976, [Pub.L. 94-583, § 3, 90 Stat. 2891](#); Nov. 19, 1988, [Pub.L. 100-702, Title II, §§ 201\(a\), 202\(a\), 203\(a\), 102 Stat. 4646](#); Oct. 19, 1996, [Pub.L. 104-317, Title II, § 205\(a\)](#), 110 Stat. 3850; Feb. 18, 2005, [Pub.L. 109-2, § 4\(a\), 119 Stat. 9](#); [Pub.L. 112-63, Title I, §§ 101, 102](#), Dec. 7, 2011, 125 Stat. 758.)

Footnotes

¹

So in original. Reference to “16(f)(3)” probably should be preceded by “section”.

²

So in original. Probably should be “77p(f)(3)”.

28 U.S.C.A. § 1332, 28 USCA § 1332

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ADD172**§ 2201. Creation of remedy, 28 USCA § 2201**



KeyCite Yellow Flag - Negative Treatment

Unconstitutional or Preempted **Negative Treatment Reconsidered by** *Florida ex rel. Atty. Gen. v. U.S. Dept. of Health and Human Services*, 11th Cir.(Fla.), Aug. 12, 2011**United States Code Annotated****Title 28. Judiciary and Judicial Procedure (Refs & Annos)****Part VI. Particular Proceedings****Chapter 151. Declaratory Judgments (Refs & Annos)****28 U.S.C.A. § 2201****§ 2201. Creation of remedy****Effective: March 23, 2010**

Currentness

(a) In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under [section 7428 of the Internal Revenue Code of 1986](#), a proceeding under [section 505](#) or [1146 of title 11](#), or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in [section 516A\(f\)\(10\) of the Tariff Act of 1930](#)), as determined by the administering authority, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

(b) For limitations on actions brought with respect to drug patents see [section 505](#) or [512 of the Federal Food, Drug, and Cosmetic Act](#), or [section 351 of the Public Health Service Act](#).

CREDIT(S)

(June 25, 1948, c. 646, 62 Stat. 964; May 24, 1949, c. 139, § 111, 63 Stat. 105; Aug. 28, 1954, c. 1033, 68 Stat. 890; July 7, 1958, Pub.L. 85-508, § 12(p), 72 Stat. 349; Oct. 4, 1976, [Pub.L. 94-455, Title XIII, § 1306\(b\)\(8\)](#), 90 Stat. 1719; Nov. 6, 1978, [Pub.L. 95-598, Title II, § 249](#), 92 Stat. 2672; Sept. 24, 1984, [Pub.L. 98-417, Title I, § 106](#), 98 Stat. 1597; Sept. 28, 1988, [Pub.L. 100-449, Title IV, § 402\(c\)](#), 102 Stat. 1884; Nov. 16, 1988, [Pub.L. 100-670, Title I, § 107\(b\)](#), 102 Stat. 3984; Dec. 8, 1993, [Pub.L. 103-182, Title IV, § 414\(b\)](#), 107 Stat. 2147; Mar. 23, 2010, [Pub.L. 111-148, Title VII, § 7002\(c\)\(2\)](#), 124 Stat. 816.)

TERMINATION OF AMENDMENT

<For termination of amendment by [section 501\(c\) of Pub.L. 100-449](#), see Sunset Provisions note set out under this section.>

ADD173

§ 2201. Creation of remedy, 28 USCA § 2201

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Current through P.L. 114-49 approved 8-7-2015

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§ 201.50 Statement of identity., 21 C.F.R. § 201.50

Code of Federal Regulations**Title 21. Food and Drugs****Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)****Subchapter C. Drugs: General****Part 201. Labeling (Refs & Annos)****Subpart B. Labeling Requirements for Prescription Drugs and/or Insulin****21 C.F.R. § 201.50****§ 201.50 Statement of identity.****Currentness**

(a) The label of prescription and insulin-containing drugs in package form shall bear as one of its principal features a statement of the identity of the drug.

(b) Such statement of identity shall be in terms of the established name of the drug. In the case of a prescription drug that is a mixture and that has no established name, the requirement for statement of identity shall be deemed to be satisfied by a listing of the quantitative ingredient information as prescribed by [§ 201.10](#).

(c) The statement of identity of a prescription drug shall also comply with the placement, size and prominence requirements of [§ 201.10](#).

Credits

[[63 FR 26698](#), May 13, 1998; [63 FR 48576](#), Sept. 11, 1998]

SOURCE: [40 FR 13998](#), March 27, 1975; [51 FR 8182](#), March 7, 1986; [51 FR 43904](#), Dec. 5, 1986; [52 FR 2111](#), Jan. 20, 1987; [53 FR 4135](#), Feb. 12, 1988; [54 FR 39635](#), Sept. 27, 1989; [57 FR 54300](#), Nov. 18, 1992; [58 FR 45201](#), Aug. 26, 1993; [62 FR 51515](#), Oct. 1, 1997; [63 FR 26698](#), May 13, 1998; [64 FR 400](#), Jan. 5, 1999, unless otherwise noted.

AUTHORITY: [21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e](#); [42 U.S.C. 216, 241, 262, 264](#).

Current through Sept. 24, 2015; [80 FR 57688](#).

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§ 201.51 Declaration of net quantity of contents., 21 C.F.R. § 201.51

Code of Federal Regulations**Title 21. Food and Drugs****Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)****Subchapter C. Drugs: General****Part 201. Labeling (Refs & Annos)****Subpart B. Labeling Requirements for Prescription Drugs and/or Insulin****21 C.F.R. § 201.51****§ 201.51 Declaration of net quantity of contents.****Currentness**

(a) The label of a prescription or insulin-containing drug in package form shall bear a declaration of the net quantity of contents. This shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The statement of quantity of drugs in tablet, capsule, ampule, or other unit dosage form shall be expressed in terms of numerical count; the statement of quantity for drugs in other dosage forms shall be in terms of weight if the drug is solid, semi-solid, or viscous, or in terms of fluid measure if the drug is liquid. When the drug quantity statement is in terms of the numerical count of the drug units, it shall be augmented to give the weight or measure of the drug units or the quantity of each active ingredient in each drug unit or, when quantity does not accurately reflect drug potency, a statement of the drug potency.

(b) Statements of weight of the contents shall in the case of prescription drugs be expressed in terms of avoirdupois pound, ounce, and grain or of kilogram, gram, and subdivisions thereof. A statement of liquid measure of the contents shall in the case of prescription drugs be expressed in terms of the U.S. gallon of 231 cubic inches and quart, pint, fluid-ounce, and fluid-dram subdivisions thereof, or of the liter and milliliter, or cubic centimeter, and shall express the volume at 68 °F. (20 °C.). A statement of the liquid measure of the contents in the case of insulin-containing drugs shall be expressed in terms of the liter and milliliter, or cubic centimeter, and shall express the volume at 68 °F. (20 °C.).

(c) The declaration shall contain only such fractions as are generally used in expressing the quantity of the drug. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

(d) The declaration shall appear as a distinct item on the label and, in the case of large volume parenterals, may be embossed on the glass.

(e) The declaration shall accurately reveal the quantity of drug in the package exclusive of wrappers and other material packed therewith.

§ 201.51 Declaration of net quantity of contents., 21 C.F.R. § 201.51

(f) A statement of the quantity of a prescription or insulin-containing drug in terms of weight or measure applicable to such drug, under the provisions of paragraph (a) of this section, shall express with prominence and conspicuousness the number of the largest whole unit, as specified in paragraph (b) of this section, that are contained in the package. Any remainder shall be expressed in terms of common or decimal fractions of such unit or in terms of the next smaller whole unit and common or decimal fractions thereof.

(g) The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large. In the case of a liquid drug in ampules or vials, intended for injection, the declaration shall be considered to express the minimum quantity and the variation above the stated measure shall comply with the excess volume prescribed by the National Formulary or the U.S. Pharmacopeia for filling of ampules. In the case of a solid drug in ampules or vials, the declaration shall be considered to express the accurate net weight. Variations shall comply with the limitations provided in the U.S. Pharmacopeia or the National Formulary.

(h) A drug shall be exempt from compliance with the net quantity declaration required by this section if it is an ointment labeled "sample", "physician's sample", or a substantially similar statement and the contents of the package do not exceed 8 grams.

SOURCE: [40 FR 13998](#), March 27, 1975; [51 FR 8182](#), March 7, 1986; [51 FR 43904](#), Dec. 5, 1986; [52 FR 2111](#), Jan. 20, 1987; [53 FR 4135](#), Feb. 12, 1988; [54 FR 39635](#), Sept. 27, 1989; [57 FR 54300](#), Nov. 18, 1992; [58 FR 45201](#), Aug. 26, 1993; [62 FR 51515](#), Oct. 1, 1997; [63 FR 26698](#), May 13, 1998; [64 FR 400](#), Jan. 5, 1999, unless otherwise noted.

AUTHORITY: [21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e](#); [42 U.S.C. 216, 241, 262, 264](#).

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§ 201.55 Statement of dosage., 21 C.F.R. § 201.55

Code of Federal Regulations**Title 21. Food and Drugs****Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)****Subchapter C. Drugs: General****Part 201. Labeling (Refs & Annos)****Subpart B. Labeling Requirements for Prescription Drugs and/or Insulin****21 C.F.R. § 201.55****§ 201.55 Statement of dosage.****Currentness**

Section 201.100(b)(2) requires that labels for prescription drugs bear a statement of the recommended or usual dosage. Since the dosage for some prescription drugs varies within extremely wide limits, depending upon the conditions being treated, it may not be possible in all cases to present an informative or useful statement of the recommended or usual dosage in the space available on the label or carton of the package. It is the view of the Food and Drug Administration that when such a situation prevails, compliance with this requirement would be met by a statement such as "See package insert for dosage information", where the detailed information is contained in such insert. However, if an informative, realistic, recommended or usual dosage can readily be set forth on the label, it should appear thereon.

SOURCE: 40 FR 13998, March 27, 1975; 51 FR 8182, March 7, 1986; 51 FR 43904, Dec. 5, 1986; 52 FR 2111, Jan. 20, 1987; 53 FR 4135, Feb. 12, 1988; 54 FR 39635, Sept. 27, 1989; 57 FR 54300, Nov. 18, 1992; 58 FR 45201, Aug. 26, 1993; 62 FR 51515, Oct. 1, 1997; 63 FR 26698, May 13, 1998; 64 FR 400, Jan. 5, 1999, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

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§ 201.56 Requirements on content and format of labeling for..., 21 C.F.R. § 201.56

Code of Federal Regulations**Title 21. Food and Drugs****Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)****Subchapter C. Drugs: General****Part 201. Labeling (Refs & Annos)****Subpart B. Labeling Requirements for Prescription Drugs and/or Insulin****21 C.F.R. § 201.56****§ 201.56 Requirements on content and format of labeling for human prescription drug and biological products.****Effective: June 30, 2015**

Currentness

(a) General requirements. Prescription drug labeling described in § 201.100(d) must meet the following general requirements:

(1) The labeling must contain a summary of the essential scientific information needed for the safe and effective use of the drug.

(2) The labeling must be informative and accurate and neither promotional in tone nor false or misleading in any particular. In accordance with §§ 314.70 and 601.12 of this chapter, the labeling must be updated when new information becomes available that causes the labeling to become inaccurate, false, or misleading.

(3) The labeling must be based whenever possible on data derived from human experience. No implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness. Conclusions based on animal data but necessary for safe and effective use of the drug in humans must be identified as such and included with human data in the appropriate section of the labeling.

(b) Categories of prescription drugs subject to the labeling content and format requirements in §§ 201.56(d) and 201.57.

(1) The following categories of prescription drug products are subject to the labeling requirements in paragraph (d) of this section and § 201.57 in accordance with the implementation schedule in paragraph (c) of this section:

(i) Prescription drug products for which a new drug application (NDA), biologics license application (BLA), or efficacy

§ 201.56 Requirements on content and format of labeling for..., 21 C.F.R. § 201.56

supplement was approved by the Food and Drug Administration (FDA) between June 30, 2001 and June 30, 2006;

(ii) Prescription drug products for which an NDA, BLA, or efficacy supplement is pending on June 30, 2006; or

(iii) Prescription drug products for which an NDA, BLA, or efficacy supplement is submitted anytime on or after June 30, 2006.

(2) Prescription drug products not described in paragraph (b)(1) of this section are subject to the labeling requirements in paragraph (e) of this section and § 201.80.

(c) Schedule for implementing the labeling content and format requirements in §§ 201.56(d) and 201.57. For products described in paragraph (b)(1) of this section, labeling conforming to the requirements in paragraph (d) of this section and § 201.57 must be submitted according to the following schedule:

(1) For products for which an NDA, BLA, or efficacy supplement is submitted for approval on or after June 30, 2006, proposed conforming labeling must be submitted as part of the application.

(2) For products for which an NDA, BLA, or efficacy supplement is pending on June 30, 2006, or that has been approved any time from June 30, 2005, up to and including June 30, 2006, a supplement with proposed conforming labeling must be submitted no later than June 30, 2009.

(3) For products for which an NDA, BLA, or efficacy supplement has been approved anytime from June 30, 2004, up to and including June 29, 2005, a supplement with proposed conforming labeling must be submitted no later than June 30, 2010.

(4) For products for which an NDA, BLA, or efficacy supplement has been approved anytime from June 30, 2003, up to and including June 29, 2004, a supplement with proposed conforming labeling must be submitted no later than June 30, 2011.

(5) For products for which an NDA, BLA, or efficacy supplement has been approved anytime from June 30, 2002, up to and including June 29, 2003, a supplement with proposed conforming labeling must be submitted no later than June 30, 2012.

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(6) For products for which an NDA, BLA, or efficacy supplement has been approved anytime from June 30, 2001, up to and including June 29, 2002, a supplement with proposed conforming labeling must be submitted no later than June 30, 2013.

(d) Labeling requirements for new and more recently approved prescription drug products. This paragraph applies only to prescription drug products described in paragraph (b)(1) of this section and must be implemented according to the schedule specified in paragraph (c) of this section.

(1) Prescription drug labeling described in [§ 201.100\(d\)](#) must contain the specific information required under § 201.57(a), (b), and (c) under the following headings and subheadings and in the following order:

Highlights of Prescribing Information

Product Names, Other Required Information

Boxed Warning

Recent Major Changes

Indications and Usage

Dosage and Administration

Dosage Forms and Strengths

Contraindications

Warnings and Precautions

Adverse Reactions

Drug Interactions

Use in Specific Populations

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Full Prescribing Information: Contents

Full Prescribing Information

Boxed Warning

1 Indications and Usage

2 Dosage and Administration

3 Dosage Forms and Strengths

4 Contraindications

5 Warnings and Precautions

6 Adverse Reactions

7 Drug Interactions

8 Use in Specific Populations

8.1 Pregnancy

8.2 Lactation

8.3 Females and Males of Reproductive Potential

8.4 Pediatric use

8.5 Geriatric use

9 Drug Abuse and Dependence

9.1 Controlled substance

§ 201.56 Requirements on content and format of labeling for..., 21 C.F.R. § 201.56

9.2 Abuse

9.3 Dependence

10 Overdosage

11 Description

12 Clinical Pharmacology

12.1 Mechanism of action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

13 Nonclinical Toxicology

13.1 Carcinogenesis, mutagenesis, impairment of fertility

13.2 Animal toxicology and/or pharmacology

14 Clinical Studies

15 References

16 How Supplied/Storage and Handling

17 Patient Counseling Information

(2) Additional nonstandard subheadings that are used to enhance labeling organization, presentation, or ease of use (e.g., for individual warnings or precautions, or for each drug interaction) must be assigned a decimal number that corresponds to their placement in labeling. The decimal numbers must be consistent with the standardized identifying numbers listed in paragraph (d)(1) of this section (e.g., subheadings added to the “Warnings and Precautions” section

§ 201.56 Requirements on content and format of labeling for..., 21 C.F.R. § 201.56

must be numbered 5.1, 5.2, and so on).

(3) Any reference in Highlights to information appearing in the full prescribing information must be accompanied by the identifying number (in parentheses) corresponding to the location of the information in the full prescribing information.

(4) Omit clearly inapplicable sections, subsections, or specific information. If sections or subsections required under paragraph (d)(1) of this section are omitted from the full prescribing information, the heading “Full Prescribing Information: Contents” must be followed by an asterisk and the following statement must appear at the end of Contents: “ * Sections or subsections omitted from the full prescribing information are not listed.”

(5) Any risk information that is required under § 201.57(c)(9)(iv) is considered “appropriate pediatric contraindications, warnings, or precautions” within the meaning of section 505A(l)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355A(l)(2)), whether such information appears in the “Contraindications,” “Warnings and Precautions,” or “Use in Specific Populations” section of labeling.

(e) Labeling requirements for older prescription drug products. This paragraph applies only to approved prescription drug products not described in paragraph (b)(1) of this section.

(1) Prescription drug labeling described in § 201.100(d) must contain the specific information required under § 201.80 under the following section headings and in the following order:

Description

Clinical Pharmacology

Indications and Usage

Contraindications

Warnings

Precautions

Adverse Reactions

§ 201.56 Requirements on content and format of labeling for..., 21 C.F.R. § 201.56

Drug Abuse and Dependence

Overdosage

Dosage and Administration

How Supplied

(2) The labeling may contain the following additional section headings if appropriate and if in compliance with § 201.80(l) and (m):

Animal Pharmacology and/or Animal Toxicology

Clinical Studies

References

(3) Omit clearly inapplicable sections, subsections, or specific information.

(4) The labeling may contain a “Product Title” section preceding the “Description” section and containing only the information required by § 201.80(a)(1)(i), (a)(1)(ii), (a)(1)(iii), and (a)(1)(iv) and § 201.100(e). The information required by § 201.80(a)(1)(i) through (a)(1)(iv) must appear in the “Description” section of the labeling, whether or not it also appears in a “Product Title.”

(5) The labeling must contain the date of the most recent revision of the labeling, identified as such, placed prominently immediately after the last section of the labeling.

(6) The requirement in § 201.80(f)(2) to reprint any FDA–approved patient labeling at the end of prescription drug labeling or accompany the prescription drug labeling must be implemented no later than June 30, 2007.

Credits

[44 FR 37462, June 26, 1979; 71 FR 3986, Jan. 24, 2006; 79 FR 72101, Dec. 4, 2014]

ADD185

§ 201.56 Requirements on content and format of labeling for..., 21 C.F.R. § 201.56

SOURCE: [40 FR 13998](#), March 27, 1975; [51 FR 8182](#), March 7, 1986; [51 FR 43904](#), Dec. 5, 1986; [52 FR 2111](#), Jan. 20, 1987; [53 FR 4135](#), Feb. 12, 1988; [54 FR 39635](#), Sept. 27, 1989; [57 FR 54300](#), Nov. 18, 1992; [58 FR 45201](#), Aug. 26, 1993; [62 FR 51515](#), Oct. 1, 1997; [63 FR 26698](#), May 13, 1998; [64 FR 400](#), Jan. 5, 1999, unless otherwise noted.

AUTHORITY: [21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e](#); [42 U.S.C. 216, 241, 262, 264](#).

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§ 201.57 Specific requirements on content and format of..., 21 C.F.R. § 201.57

Code of Federal Regulations**Title 21. Food and Drugs****Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)****Subchapter C. Drugs: General****Part 201. Labeling (Refs & Annos)****Subpart B. Labeling Requirements for Prescription Drugs and/or Insulin****21 C.F.R. § 201.57**

§ 201.57 Specific requirements on content and format of labeling for human prescription drug and biological products described in § 201.56(b)(1).

Effective: June 30, 2015

Currentness

The requirements in this section apply only to prescription drug products described in § 201.56(b)(1) and must be implemented according to the schedule specified in § 201.56(c), except for the requirement in paragraph (c)(18) of this section to reprint any FDA-approved patient labeling at the end of prescription drug labeling or accompany the prescription drug labeling, which must be implemented no later than June 30, 2007.

(a) Highlights of prescribing information. The following information must appear in all prescription drug labeling:

(1) Highlights limitation statement. The verbatim statement “These highlights do not include all the information needed to use (insert name of drug product) safely and effectively. See full prescribing information for (insert name of drug product).”

(2) Drug names, dosage form, route of administration, and controlled substance symbol. The proprietary name and the established name of the drug, if any, as defined in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act (the act) or, for biological products, the proper name (as defined in § 600.3 of this chapter) including any appropriate descriptors. This information must be followed by the drug’s dosage form and route of administration. For controlled substances, the controlled substance symbol designating the schedule in which the controlled substance is listed must be included as required by § 1302.04 of this chapter.

(3) Initial U.S. approval. The verbatim statement “Initial U.S. Approval” followed by the four-digit year in which FDA initially approved a new molecular entity, new biological product, or new combination of active ingredients. The statement must be placed on the line immediately beneath the established name or, for biological products, proper name of the product.

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(4) **Boxed warning.** A concise summary of any boxed warning required by paragraph (c)(1) of this section, not to exceed a length of 20 lines. The summary must be preceded by a heading, in upper-case letters, containing the word “WARNING” and other words that are appropriate to identify the subject of the warning. The heading and the summary must be contained within a box and bolded. The following verbatim statement must be placed immediately following the heading of the boxed warning: “See full prescribing information for complete boxed warning.”

(5) **Recent major changes.** A list of the section(s) of the full prescribing information, limited to the labeling sections described in paragraphs (c)(1), (c)(2), (c)(3), (c)(5), and (c)(6) of this section, that contain(s) substantive labeling changes that have been approved by FDA or authorized under § 314.70(c)(6) or (d)(2), or § 601.12(f)(1) through (f)(3) of this chapter. The heading(s) and, if appropriate, the subheading(s) of the labeling section(s) affected by the change must be listed together with each section’s identifying number and the date (month/year) on which the change was incorporated in labeling. These labeling sections must be listed in the order in which they appear in the full prescribing information. A changed section must be listed under this heading in Highlights for at least 1 year after the date of the labeling change and must be removed at the first printing subsequent to the 1 year period.

(6) **Indications and usage.** A concise statement of each of the product’s indications, as required under paragraph (c)(2) of this section, with any appropriate subheadings. Major limitations of use (e.g., lack of effect in particular subsets of the population, or second line therapy status) must be briefly noted. If the product is a member of an established pharmacologic class, the concise statement under this heading in Highlights must identify the class in the following manner: “(Drug) is a (name of class) indicated for (indication(s)).”

(7) **Dosage and administration.** A concise summary of the information required under paragraph (c)(3) of this section, with any appropriate subheadings, including the recommended dosage regimen, starting dose, dose range, critical differences among population subsets, monitoring recommendations, and other clinically significant clinical pharmacologic information.

(8) **Dosage forms and strengths.** A concise summary of the information required under paragraph (c)(4) of this section, with any appropriate subheadings (e.g., tablets, capsules, injectable, suspension), including the strength or potency of the dosage form in metric system (e.g., 10–milligram tablets) and whether the product is scored.

(9) **Contraindications.** A concise statement of each of the product’s contraindications, as required under paragraph (c)(5) of this section, with any appropriate subheadings.

(10) **Warnings and precautions.** A concise summary of the most clinically significant information required under paragraph (c)(6) of this section, with any appropriate subheadings, including information that would affect decisions about whether to prescribe a drug, recommendations for patient monitoring that are critical to safe use of the drug, and measures that can be taken to prevent or mitigate harm.

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(11) Adverse reactions.

(i) A list of the most frequently occurring adverse reactions, as described in paragraph (c)(7) of this section, along with the criteria used to determine inclusion (e.g., incidence rate). Adverse reactions important for other reasons (e.g., because they are serious or frequently lead to discontinuation or dosage adjustment) must not be repeated under this heading in Highlights if they are included elsewhere in Highlights (e.g., Warnings and Precautions, Contraindications).

(ii) For drug products other than vaccines, the verbatim statement “To report SUSPECTED ADVERSE REACTIONS, contact (insert name of manufacturer) at (insert manufacturer’s phone number) or FDA at (insert current FDA phone number and Web address for voluntary reporting of adverse reactions).”

(iii) For vaccines, the verbatim statement “To report SUSPECTED ADVERSE REACTIONS, contact (insert name of manufacturer) at (insert manufacturer’s phone number) or VAERS at (insert the current VAERS phone number and Web address for voluntary reporting of adverse reactions).”

(iv) For manufacturers with a Web site for voluntary reporting of adverse reactions, the Web address of the direct link to the site.

(12) Drug interactions. A concise summary of the information required under paragraph (c)(8) of this section, with any appropriate subheadings.

(13) Use in specific populations. A concise summary of the information required under paragraph (c)(9) of this section, with any appropriate subheadings.

(14) Patient counseling information statement. The verbatim statement “See 17 for Patient Counseling Information” or, if the product has FDA–approved patient labeling, the verbatim statement “See 17 for Patient Counseling Information and (insert either FDA–approved patient labeling or Medication Guide).”

(15) Revision date. The date of the most recent revision of the labeling, identified as such, placed at the end of Highlights.

(b) Full prescribing information: Contents. Contents must contain a list of each heading and subheading required in the full prescribing information under § 201.56(d)(1), if not omitted under § 201.56(d)(4), preceded by the identifying number required under § 201.56(d)(1). Contents must also contain any additional subheading(s) included in the full prescribing information preceded by the identifying number assigned in accordance with § 201.56(d)(2).

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(c) Full prescribing information. The full prescribing information must contain the information in the order required under paragraphs (c)(1) through (c)(18) of this section, together with the headings, subheadings, and identifying numbers required under § 201.56(d)(1), unless omitted under § 201.56(d)(4). If additional subheadings are used within a labeling section, they must be preceded by the identifying number assigned in accordance with § 201.56(d)(2).

(1) Boxed warning. Certain contraindications or serious warnings, particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box. The boxed warning ordinarily must be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. The box must contain, in uppercase letters, a heading inside the box that includes the word “WARNING” and conveys the general focus of the information in the box. The box must briefly explain the risk and refer to more detailed information in the “Contraindications” or “Warnings and Precautions” section, accompanied by the identifying number for the section or subsection containing the detailed information.

(2) 1 Indications and usage. This section must state that the drug is indicated for the treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition, or of a manifestation of a recognized disease or condition, or for the relief of symptoms associated with a recognized disease or condition.

(i) This section must include the following information when the conditions listed are applicable:

(A) If the drug is used for an indication only in conjunction with a primary mode of therapy (e.g., diet, surgery, behavior changes, or some other drug), a statement that the drug is indicated as an adjunct to that mode of therapy.

(B) If evidence is available to support the safety and effectiveness of the drug or biological product only in selected subgroups of the larger population (e.g., patients with mild disease or patients in a special age group), or if the indication is approved based on a surrogate endpoint under § 314.510 or § 601.41 of this chapter, a succinct description of the limitations of usefulness of the drug and any uncertainty about anticipated clinical benefits, with reference to the “Clinical Studies” section for a discussion of the available evidence.

(C) If specific tests are necessary for selection or monitoring of the patients who need the drug (e.g., microbe susceptibility tests), the identity of such tests.

(D) If information on limitations of use or uncertainty about anticipated clinical benefits is relevant to the recommended intervals between doses, to the appropriate duration of treatment when such treatment should be limited, or to any modification of dosage, a concise description of the information with reference to the more detailed information in the “Dosage and Administration” section.

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(E) If safety considerations are such that the drug should be reserved for specific situations (e.g., cases refractory to other drugs), a statement of the information.

(F) If there are specific conditions that should be met before the drug is used on a long term basis (e.g., demonstration of responsiveness to the drug in a short term trial in a given patient), a statement of the conditions; or, if the indications for long term use are different from those for short term use, a statement of the specific indications for each use.

(ii) If there is a common belief that the drug may be effective for a certain use or if there is a common use of the drug for a condition, but the preponderance of evidence related to the use or condition shows that the drug is ineffective or that the therapeutic benefits of the product do not generally outweigh its risks, FDA may require that this section state that there is a lack of evidence that the drug is effective or safe for that use or condition.

(iii) Any statements comparing the safety or effectiveness of the drug with other agents for the same indication must, except for biological products, be supported by substantial evidence derived from adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless this requirement is waived under § 201.58 or § 314.126(c) of this chapter. For biological products, such statements must be supported by substantial evidence.

(iv) For drug products other than biological products, all indications listed in this section must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless the requirement is waived under § 201.58 or § 314.126(c) of this chapter. Indications or uses must not be implied or suggested in other sections of the labeling if not included in this section.

(v) For biological products, all indications listed in this section must be supported by substantial evidence of effectiveness. Indications or uses must not be implied or suggested in other sections of the labeling if not included in this section.

(3) 2 Dosage and administration.

(i) This section must state the recommended dose and, as appropriate:

(A) The dosage range,

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- (B) An upper limit beyond which safety and effectiveness have not been established, or beyond which increasing the dose does not result in increasing effectiveness,
 - (C) Dosages for each indication and subpopulation,
 - (D) The intervals recommended between doses,
 - (E) The optimal method of titrating dosage,
 - (F) The usual duration of treatment when treatment duration should be limited,
 - (G) Dosing recommendations based on clinical pharmacologic data (e.g., clinically significant food effects),
 - (H) Modification of dosage needed because of drug interactions or in special patient populations (e.g., in children, in geriatric age groups, in groups defined by genetic characteristics, or in patients with renal or hepatic disease),
 - (I) Important considerations concerning compliance with the dosage regimen,
 - (J) Efficacious or toxic concentration ranges and therapeutic concentration windows of the drug or its metabolites, if established and clinically significant. Information on therapeutic drug concentration monitoring (TDM) must also be included in this section when TDM is necessary.
- (ii) Dosing regimens must not be implied or suggested in other sections of the labeling if not included in this section.
- (iii) Radiation dosimetry information must be stated for both the patient receiving a radioactive drug and the person administering it.
- (iv) This section must also contain specific direction on dilution, preparation (including the strength of the final dosage solution, when prepared according to instructions, in terms of milligrams of active ingredient per milliliter of reconstituted solution, unless another measure of the strength is more appropriate), and administration of the dosage form, if needed (e.g., the rate of administration of parenteral drug in milligrams per minute; storage conditions for

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stability of the reconstituted drug, when important; essential information on drug incompatibilities if the drug is mixed in vitro with other drugs or diluents; and the following verbatim statement for parenterals: “Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.”)

(4) 3 Dosage forms and strengths. This section must contain information on the available dosage forms to which the labeling applies and for which the manufacturer or distributor is responsible, including:

(i) The strength or potency of the dosage form in metric system (e.g., 10 milligram tablets), and, if the apothecary system is used, a statement of the strength in parentheses after the metric designation; and

(ii) A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, and imprinting, when applicable. The National Drug Code number(s) for the drug product must not be included in this section.

(5) 4 Contraindications. This section must describe any situations in which the drug should not be used because the risk of use (e.g., certain potentially fatal adverse reactions) clearly outweighs any possible therapeutic benefit. Those situations include use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by the drug and for whom no potential benefit makes the risk acceptable. Known hazards and not theoretical possibilities must be listed (e.g., if severe hypersensitivity to the drug has not been demonstrated, it should not be listed as a contraindication). If no contraindications are known, this section must state “None.”

(6) 5 Warnings and precautions.

(i) General. This section must describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug), other potential safety hazards (including those that are expected for the pharmacological class or those resulting from drug/drug interactions), limitations in use imposed by them (e.g., avoiding certain concomitant therapy), and steps that should be taken if they occur (e.g., dosage modification). The frequency of all clinically significant adverse reactions and the approximate mortality and morbidity rates for patients experiencing the reaction, if known and necessary for the safe and effective use of the drug, must be expressed as provided under paragraph (c)(7) of this section. In accordance with §§ 314.70 and 601.12 of this chapter, the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established. A specific warning relating to a use not provided for under the “Indications and Usage” section may be required by FDA in accordance with sections 201(n) and 502(a) of the act if the drug is commonly prescribed for a disease or condition and such usage is associated with a clinically significant risk or hazard.

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(ii) Other special care precautions. This section must contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug (e.g., precautions not required under any other specific section or subsection).

(iii) Monitoring: Laboratory tests. This section must identify any laboratory tests helpful in following the patient's response or in identifying possible adverse reactions. If appropriate, information must be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be performed before, during, and after therapy.

(iv) Interference with laboratory tests. This section must briefly note information on any known interference by the product with laboratory tests and reference the section where the detailed information is presented (e.g., "Drug Interactions" section).

(7) 6 Adverse reactions. This section must describe the overall adverse reaction profile of the drug based on the entire safety database. For purposes of prescription drug labeling, an adverse reaction is an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence. This definition does not include all adverse events observed during use of a drug, only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.

(i) Listing of adverse reactions. This section must list the adverse reactions that occur with the drug and with drugs in the same pharmacologically active and chemically related class, if applicable. The list or lists must be preceded by the information necessary to interpret the adverse reactions (e.g., for clinical trials, total number exposed, extent and nature of exposure).

(ii) Categorization of adverse reactions. Within a listing, adverse reactions must be categorized by body system, by severity of the reaction, or in order of decreasing frequency, or by a combination of these, as appropriate. Within a category, adverse reactions must be listed in decreasing order of frequency. If frequency information cannot be reliably determined, adverse reactions must be listed in decreasing order of severity.

(A) Clinical trials experience. This section must list the adverse reactions identified in clinical trials that occurred at or above a specified rate appropriate to the safety database. The rate of occurrence of an adverse reaction for the drug and comparators (e.g., placebo) must be presented, unless such data cannot be determined or presentation of comparator rates would be misleading. If adverse reactions that occurred below the specified rate are included, they must be included in a separate listing. If comparative rates of occurrence cannot be reliably determined (e.g., adverse reactions were observed only in the uncontrolled trial portion of the overall safety database), adverse reactions must be grouped within specified frequency ranges as appropriate to the safety database for the drug (e.g., adverse reactions occurring at a rate of less than 1/100, adverse reactions occurring at a rate of less than 1/500) or descriptively identified, if frequency ranges cannot be determined. For adverse reactions with significant clinical implications, the listings must be supplemented with additional detail about the nature, frequency, and severity of

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the adverse reaction and the relationship of the adverse reaction to drug dose and demographic characteristics, if data are available and important.

(B) Postmarketing experience. This section of the labeling must list the adverse reactions, as defined in paragraph (c)(7) of this section, that are identified from domestic and foreign spontaneous reports. This listing must be separate from the listing of adverse reactions identified in clinical trials.

(iii) Comparisons of adverse reactions between drugs. For drug products other than biological products, any claim comparing the drug to which the labeling applies with other drugs in terms of frequency, severity, or character of adverse reactions must be based on adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless this requirement is waived under § 201.58 or § 314.126(c) of this chapter. For biological products, any such claim must be based on substantial evidence.

(8) 7 Drug interactions.

(i) This section must contain a description of clinically significant interactions, either observed or predicted, with other prescription or over-the-counter drugs, classes of drugs, or foods (e.g., dietary supplements, grapefruit juice), and specific practical instructions for preventing or managing them. The mechanism(s) of the interaction, if known, must be briefly described. Interactions that are described in the “Contraindications” or “Warnings and Precautions” sections must be discussed in more detail under this section. Details of drug interaction pharmacokinetic studies that are included in the “Clinical Pharmacology” section that are pertinent to clinical use of the drug must not be repeated in this section.

(ii) This section must also contain practical guidance on known interference of the drug with laboratory tests.

(9) 8 Use in specific populations. This section must contain the following subsections:

(i) 8.1 Pregnancy. This subsection of the labeling must contain the following information in the following order under the subheadings “Pregnancy Exposure Registry,” “Risk Summary,” “Clinical Considerations,” and “Data”:

(A) Pregnancy exposure registry. If there is a scientifically acceptable pregnancy exposure registry for the drug, contact information needed to enroll in the registry or to obtain information about the registry must be provided following the statement: “There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to (name of drug) during pregnancy.”

(B) Risk summary. The Risk Summary must contain risk statement(s) based on data from all relevant sources

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(human, animal, and/or pharmacologic) that describe, for the drug, the risk of adverse developmental outcomes (i.e., structural abnormalities, embryo-fetal and/or infant mortality, functional impairment, alterations to growth). When multiple data sources are available, the statements must be presented in the following order: Human, animal, pharmacologic. The source(s) of the data must be stated. The labeling must state the percentage range of live births in the United States with a major birth defect and the percentage range of pregnancies in the United States that end in miscarriage, regardless of drug exposure. If such information is available for the population(s) for which the drug is labeled, it must also be included. When use of a drug is contraindicated during pregnancy, this information must be stated first in the Risk Summary. When applicable, risk statements as described in paragraphs (c)(9)(i)(B)(1) and (2) of this section must include a cross-reference to additional details in the relevant portion of the “Data” subheading in the “Pregnancy” subsection of the labeling. If data demonstrate that a drug is not systemically absorbed following a particular route of administration, the Risk Summary must contain only the following statement: “(Name of drug) is not absorbed systemically following (route of administration), and maternal use is not expected to result in fetal exposure to the drug.”

(1) Risk statement based on human data. When human data are available that establish the presence or absence of any adverse developmental outcome(s) associated with maternal use of the drug, the Risk Summary must summarize the specific developmental outcome(s); their incidence; and the effects of dose, duration of exposure, and gestational timing of exposure. If human data indicate that there is an increased risk for a specific adverse developmental outcome in infants born to women exposed to the drug during pregnancy, this risk must be quantitatively compared to the risk for the same outcome in infants born to women who were not exposed to the drug but who have the disease or condition for which the drug is indicated to be used. When risk information is not available for women with the disease or condition for which the drug is indicated, the risk for the specific outcome must be compared to the rate at which the outcome occurs in the general population. The Risk Summary must state when there are no human data or when available human data do not establish the presence or absence of drug-associated risk.

(2) Risk statement based on animal data. When animal data are available, the Risk Summary must summarize the findings in animals and based on these findings, describe, for the drug, the potential risk of any adverse developmental outcome(s) in humans. This statement must include: The number and type(s) of species affected, timing of exposure, animal doses expressed in terms of human dose or exposure equivalents, and outcomes for pregnant animals and offspring. When animal studies do not meet current standards for nonclinical developmental toxicity studies, the Risk Summary must so state. When there are no animal data, the Risk Summary must so state.

(3) Risk statement based on pharmacology. When the drug has a well-understood mechanism of action that may result in adverse developmental outcome(s), the Risk Summary must explain the mechanism of action and the potential associated risks.

(C) Clinical considerations. Under the subheading “Clinical Considerations,” the labeling must provide relevant information, to the extent it is available, under the headings “Disease-associated maternal and/or embryo/fetal risk,” “Dose adjustments during pregnancy and the postpartum period,” “Maternal adverse reactions,” “Fetal/Neonatal adverse reactions,” and “Labor or delivery”:

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(1) Disease-associated maternal and/or embryo/fetal risk. If there is a serious known or potential risk to the pregnant woman and/or the embryo/fetus associated with the disease or condition for which the drug is indicated to be used, the labeling must describe the risk.

(2) Dose adjustments during pregnancy and the postpartum period. If there are pharmacokinetic data that support dose adjustment(s) during pregnancy and the postpartum period, a summary of this information must be provided.

(3) Maternal adverse reactions. If use of the drug is associated with a maternal adverse reaction that is unique to pregnancy or if a known adverse reaction occurs with increased frequency or severity in pregnant women, the labeling must describe the adverse reaction and available intervention(s) for monitoring or mitigating the reaction. The labeling must describe, if known, the effect of dose, timing, and duration of exposure on the risk to the pregnant woman of experiencing the adverse reaction.

(4) Fetal/Neonatal adverse reactions. If it is known or anticipated that treatment of the pregnant woman increases or may increase the risk of an adverse reaction in the fetus or neonate, the labeling must describe the adverse reaction, the potential severity and reversibility of the adverse reaction, and available intervention(s) for monitoring or mitigating the reaction. The labeling must describe, if known, the effect of dose, timing, and duration of exposure on the risk.

(5) Labor or delivery. If the drug is expected to affect labor or delivery, the labeling must provide information about the effect of the drug on the pregnant woman and the fetus or neonate; the effect of the drug on the duration of labor and delivery; any increased risk of adverse reactions, including their potential severity and reversibility; and must provide information about available intervention(s) that can mitigate these effects and/or adverse reactions. The information described under this heading is not required for drugs approved for use only during labor and delivery.

(D) Data—

(1) “Data” subheading. Under the subheading “Data,” the labeling must describe the data that are the basis for the Risk Summary and Clinical Considerations.

(2) Human and animal data headings. Human and animal data must be presented separately, beneath the headings “Human Data” and “Animal Data,” and human data must be presented first.

(3) Description of human data. For human data, the labeling must describe adverse developmental outcomes, adverse reactions, and other adverse effects. To the extent applicable, the labeling must describe the types of

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studies or reports, number of subjects and the duration of each study, exposure information, and limitations of the data. Both positive and negative study findings must be included.

(4) Description of animal data. For animal data, the labeling must describe the following: Types of studies, animal species, dose, duration and timing of exposure, study findings, presence or absence of maternal toxicity, and limitations of the data. Description of maternal and offspring findings must include dose-response and severity of adverse developmental outcomes. Animal doses or exposures must be described in terms of human dose or exposure equivalents and the basis for those calculations must be included.

(ii) 8.2 Lactation. This subsection of the labeling must contain the following information in the following order under the subheadings “Risk Summary,” “Clinical Considerations,” and “Data”:

(A) Risk summary. When relevant human and/or animal lactation data are available, the Risk Summary must include a cross-reference to the “Data” subheading in the “Lactation” subsection of the labeling. When human data are available, animal data must not be included unless the animal model is specifically known to be predictive for humans. When use of a drug is contraindicated during breastfeeding, this information must be stated first in the Risk Summary.

(1) Drug not absorbed systemically. If data demonstrate that the drug is not systemically absorbed by the mother, the Risk Summary must contain only the following statement: “(Name of drug) is not absorbed systemically by the mother following (route of administration), and breastfeeding is not expected to result in exposure of the child to (name of drug).”

(2) Drug absorbed systemically. If the drug is absorbed systemically, the Risk Summary must describe the following to the extent relevant information is available:

(i) Presence of drug in human milk. The Risk Summary must state whether the drug and/or its active metabolite(s) are present in human milk. If there are no data to assess this, the Risk Summary must so state. If studies demonstrate that the drug and/or its active metabolite(s) are not detectable in human milk, the Risk Summary must state the limits of the assay used. If studies demonstrate the presence of the drug and/or its active metabolite(s) in human milk, the Risk Summary must state the concentration of the drug and/or its active metabolite(s) in human milk and the actual or estimated daily dose for an infant fed exclusively with human milk. The actual or estimated amount of the drug and/or its active metabolite(s) ingested by the infant must be compared to the labeled infant or pediatric dose, if available, or to the maternal dose. If studies demonstrate the presence of the drug and/or its active metabolite(s) in human milk but the drug and/or its active metabolite(s) are not expected to be systemically bioavailable to the breast-fed child, the Risk Summary must describe the disposition of the drug and/or its active metabolite(s). If only animal lactation data are available, the Risk Summary must state only whether or not the drug and/or its active metabolite(s) were detected in animal milk and specify the animal species.

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(ii) Effects of drug on the breast-fed child. The Risk Summary must include information, on the known or predicted effects on the child from exposure to the drug and/or its active metabolite(s) through human milk or from contact with breast or nipple skin (for topical products). The Risk Summary also must include information on systemic and/or local adverse reactions. If there are no data to assess the effects of the drug and/or its active metabolite(s) on the breast-fed child, the Risk Summary must so state.

(iii) Effects of drug on milk production. The Risk Summary must describe the effects of the drug and/or its active metabolite(s) on milk production. If there are no data to assess the effects of the drug and/or its active metabolite(s) on milk production, the Risk Summary must so state.

(3) Risk and benefit statement. For drugs absorbed systemically, unless breastfeeding is contraindicated during drug therapy, the following risk and benefit statement must appear at the end of the Risk Summary: “The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for (name of drug) and any potential adverse effects on the breast-fed child from (name of drug) or from the underlying maternal condition.”

(B) Clinical considerations. Under “Clinical Considerations,” the following information must be provided to the extent it is available and relevant:

(1) Minimizing exposure. The labeling must describe ways to minimize exposure in the breast-fed child if: The drug and/or its active metabolite(s) are present in human milk in clinically relevant concentrations; the drug does not have an established safety profile in infants; and the drug is used either intermittently, in single doses, or for short courses of therapy. When applicable, the labeling must also describe ways to minimize a breast-fed child’s oral intake of topical drugs applied to the breast or nipple skin.

(2) Monitoring for adverse reactions. The labeling must describe available intervention(s) for monitoring or mitigating the adverse reaction(s) presented in the Risk Summary.

(C) Data. Under the subheading “Data,” the labeling must describe the data that are the basis for the Risk Summary and Clinical Considerations.

(iii) 8.3 Females and males of reproductive potential. When pregnancy testing and/or contraception are required or recommended before, during, or after drug therapy and/or when there are human and/or animal data that suggest drug-associated fertility effects, this subsection of labeling must contain this information under the subheadings “Pregnancy Testing,” “Contraception,” and “Infertility,” in that order.

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(iv) 8.4 Pediatric use.

(A) Pediatric population(s)/pediatric patient(s): For the purposes of paragraphs (c)(9)(iv)(B) through (c)(9)(iv)(H) of this section, the terms pediatric population(s) and pediatric patient(s) are defined as the pediatric age group, from birth to 16 years, including age groups often called neonates, infants, children, and adolescents.

(B) If there is a specific pediatric indication different from those approved for adults that is supported by adequate and well-controlled studies in the pediatric population, it must be described under the “Indications and Usage” section, and appropriate pediatric dosage information must be given under the “Dosage and Administration” section. The “Pediatric use” subsection must cite any limitations on the pediatric indication, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. Data summarized in this subsection should be discussed in more detail, if appropriate, under the “Clinical Pharmacology” or “Clinical Studies” section. As appropriate, this information must also be contained in the “Contraindications” and/or “Warnings and Precautions” section(s).

(C) If there are specific statements on pediatric use of the drug for an indication also approved for adults that are based on adequate and well-controlled studies in the pediatric population, they must be summarized in the “Pediatric use” subsection and discussed in more detail, if appropriate, under the “Clinical Pharmacology” and “Clinical Studies” sections. Appropriate pediatric dosage must be given under the “Dosage and Administration” section. The “Pediatric use” subsection of the labeling must also cite any limitations on the pediatric use statement, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. As appropriate, this information must also be contained in the “Contraindications” and/or “Warnings and Precautions” section(s).

(D)(1) When a drug is approved for pediatric use based on adequate and well-controlled studies in adults with other information supporting pediatric use, the “Pediatric use” subsection of the labeling must contain either the following statement or a reasonable alternative:

The safety and effectiveness of (drug name) have been established in the age groups ____ to ____ (note any limitations, e.g., no data for pediatric patients under 2, or only applicable to certain indications approved in adults). Use of (drug name) in these age groups is supported by evidence from adequate and well-controlled studies of (drug name) in adults with additional data (insert wording that accurately describes the data submitted to support a finding of substantial evidence of effectiveness in the pediatric population).

(2) Data summarized in the preceding prescribed statement in this subsection must be discussed in more detail, if appropriate, under the “Clinical Pharmacology” or the “Clinical Studies” section. For example, pediatric pharmacokinetic or pharmacodynamic studies and dose response information should be described in the “Clinical Pharmacology” section. Pediatric dosing instructions must be included in the “Dosage and

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Administration” section. Any differences between pediatric and adult responses, need for specific monitoring, dosing adjustments, and any other information related to safe and effective use of the drug in pediatric patients must be cited briefly in the “Pediatric use” subsection and, as appropriate, in the “Contraindications,” “Warnings and Precautions,” and “Dosage and Administration” sections.

(E) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for a particular pediatric population, the “Pediatric use” subsection must contain an appropriate statement such as “Safety and effectiveness in pediatric patients below the age of (____) have not been established.” If use of the drug in this pediatric population is associated with a specific hazard, the hazard must be described in this subsection, or, if appropriate, the hazard must be stated in the “Contraindications” or “Warnings and Precautions” section and this subsection must refer to it.

(F) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for any pediatric population, this subsection must contain the following statement: “Safety and effectiveness in pediatric patients have not been established.” If use of the drug in premature or neonatal infants, or other pediatric subgroups, is associated with a specific hazard, the hazard must be described in this subsection, or, if appropriate, the hazard must be stated in the “Contraindications” or “Warnings and Precautions” section and this subsection must refer to it.

(G) If the sponsor believes that none of the statements described in paragraphs (c)(9)(iv)(B) through (c)(9)(iv)(F) of this section are appropriate or relevant to the labeling of a particular drug, the sponsor must provide reasons for omission of the statements and may propose alternative statement(s). FDA may permit use of an alternative statement if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug’s labeling and that the alternative statement is accurate and appropriate.

(H) If the drug product contains one or more inactive ingredients that present an increased risk of toxic effects to neonates or other pediatric subgroups, a special note of this risk must be made, generally in the “Contraindications” or “Warnings and Precautions” section.

(v) 8.5 Geriatric use.

(A) A specific geriatric indication, if any, that is supported by adequate and well-controlled studies in the geriatric population must be described under the “Indications and Usage” section, and appropriate geriatric dosage must be stated under the “Dosage and Administration” section. The “Geriatric use” subsection must cite any limitations on the geriatric indication, need for specific monitoring, specific hazards associated with the geriatric indication, and other information related to the safe and effective use of the drug in the geriatric population. Unless otherwise noted, information contained in the “Geriatric use” subsection must pertain to use of the drug in persons 65 years of age and older. Data summarized in this subsection must be discussed in more detail, if appropriate, under “Clinical Pharmacology” or the “Clinical Studies” section. As appropriate, this information must also be contained in the “Warnings and Precautions” and/or “Contraindications” section(s).

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(B) Specific statements on geriatric use of the drug for an indication approved for adults generally, as distinguished from a specific geriatric indication, must be contained in the “Geriatric use” subsection and must reflect all information available to the sponsor that is relevant to the appropriate use of the drug in elderly patients. This information includes detailed results from controlled studies that are available to the sponsor and pertinent information from well-documented studies obtained from a literature search. Controlled studies include those that are part of the marketing application and other relevant studies available to the sponsor that have not been previously submitted in the investigational new drug application, new drug application, biologics license application, or a supplement or amendment to one of these applications (e.g., postmarketing studies or adverse drug reaction reports). The “Geriatric use” subsection must contain the following statement(s) or reasonable alternative, as applicable, taking into account available information:

(1) If clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects, and other reported clinical experience has not identified such differences, the “Geriatric use” subsection must include the following statement:

Clinical studies of (name of drug) did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

(2) If clinical studies (including studies that are part of marketing applications and other relevant studies available to the sponsor that have not been submitted in the sponsor’s applications) included enough elderly subjects to make it likely that differences in safety or effectiveness between elderly and younger subjects would have been detected, but no such differences (in safety or effectiveness) were observed, and other reported clinical experience has not identified such differences, the “Geriatric use” subsection must contain the following statement:

Of the total number of subjects in clinical studies of (name of drug), ____ percent were 65 and over, while ____ percent were 75 and over. (Alternatively, the labeling may state the total number of subjects included in the studies who were 65 and over and 75 and over.) No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

(3) If evidence from clinical studies and other reported clinical experience available to the sponsor indicates that use of the drug in elderly patients is associated with differences in safety or effectiveness, or requires specific monitoring or dosage adjustment, the “Geriatric use” subsection must contain a brief description of observed differences or specific monitoring or dosage requirements and, as appropriate, must refer to more detailed discussions in the “Contraindications,” “Warnings and Precautions,” “Dosage and Administration,” or other sections.

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(C)(1) If specific pharmacokinetic or pharmacodynamic studies have been carried out in the elderly, they must be described briefly in the “Geriatric use” subsection and in detail under the “Clinical Pharmacology” section. The “Clinical Pharmacology” and “Drug Interactions” sections ordinarily contain information on drug/disease and drug/drug interactions that is particularly relevant to the elderly, who are more likely to have concomitant illness and to use concomitant drugs.

(2) If a drug is known to be substantially excreted by the kidney, the “Geriatric use” subsection must include the statement:

This drug is known to be substantially excreted by the kidney, and the risk of adverse reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

(D) If use of the drug in the elderly appears to cause a specific hazard, the hazard must be described in the “Geriatric use” subsection, or, if appropriate, the hazard must be stated in the “Contraindications” or “Warnings and Precautions” section, and the “Geriatric use” subsection must refer to those sections.

(E) Labeling under paragraphs (c)(9)(v)(A) through (c)(9)(v)(C) of this section may include statements, if they are necessary for safe and effective use of the drug, and reflect good clinical practice or past experience in a particular situation, e.g., for a sedating drug, it could be stated that:

Sedating drugs may cause confusion and over-sedation in the elderly; elderly patients generally should be started on low doses of (name of drug) and observed closely.

(F) If the sponsor believes that none of the requirements described in paragraphs (c)(9)(v)(A) through (c)(9)(v)(E) of this section are appropriate or relevant to the labeling of a particular drug, the sponsor must provide reasons for omission of the statements and may propose an alternative statement. FDA may permit omission of the statements if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug’s labeling. FDA may permit use of an alternative statement if the agency determines that such statement is accurate and appropriate.

(vi) Additional subsections. Additional subsections may be included, as appropriate, if sufficient data are available concerning the use of the drug in other specified subpopulations (e.g., renal or hepatic impairment).

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(10) 9 Drug abuse and dependence. This section must contain the following information, as appropriate:

(i) 9.1 Controlled substance. If the drug is controlled by the Drug Enforcement Administration, the schedule in which it is controlled must be stated.

(ii) 9.2 Abuse. This subsection must state the types of abuse that can occur with the drug and the adverse reactions pertinent to them, and must identify particularly susceptible patient populations. This subsection must be based primarily on human data and human experience, but pertinent animal data may also be used.

(iii) 9.3 Dependence. This subsection must describe characteristic effects resulting from both psychological and physical dependence that occur with the drug and must identify the quantity of the drug over a period of time that may lead to tolerance or dependence, or both. Details must be provided on the adverse effects of chronic abuse and the effects of abrupt withdrawal. Procedures necessary to diagnose the dependent state and the principles of treating the effects of abrupt withdrawal must be described.

(11) 10 Overdosage. This section must be based on human data. If human data are unavailable, appropriate animal and in vitro data may be used. The following specific information must be provided:

(i) Signs, symptoms, and laboratory findings associated with an overdosage of the drug;

(ii) Complications that can occur with the drug (for example, organ toxicity or delayed acidosis);

(iii) Concentrations of the drug in biologic fluids associated with toxicity or death; physiologic variables influencing excretion of the drug, such as urine pH; and factors that influence the dose response relationship of the drug, such as tolerance. The pharmacokinetic data given in the "Clinical Pharmacology" section also may be referenced here, if applicable to overdoses;

(iv) The amount of the drug in a single dose that is ordinarily associated with symptoms of overdosage and the amount of the drug in a single dose that is likely to be life threatening;

(v) Whether the drug is dialyzable; and

(vi) Recommended general treatment procedures and specific measures for support of vital functions (e.g., proven

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antidotes, gastric lavage, forced diuresis, or as per Poison Control Center). Such recommendations must be based on data available for the specific drug or experience with pharmacologically related drugs. Unqualified recommendations for which data are lacking for the specific drug or class of drugs must not be stated.

(12) 11 Description.

(i) This section must contain:

(A) The proprietary name and the established name, if any, as defined in section 502(e)(2) of the act, of the drug or, for biological products, the proper name (as defined in § 600.3 of this chapter) and any appropriate descriptors;

(B) The type of dosage form(s) and the route(s) of administration to which the labeling applies;

(C) The same qualitative and/or quantitative ingredient information as required under § 201.100(b) for drug labels or §§ 610.60 and 610.61 of this chapter for biological product labels;

(D) If the product is sterile, a statement of that fact;

(E) The pharmacological or therapeutic class of the drug;

(F) For drug products other than biological products, the chemical name and structural formula of the drug; and

(G) If the product is radioactive, a statement of the important nuclear physical characteristics, such as the principal radiation emission data, external radiation, and physical decay characteristics.

(ii) If appropriate, other important chemical or physical information, such as physical constants or pH, must be stated.

(13) 12 Clinical pharmacology.

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(i) This section must contain information relating to the human clinical pharmacology and actions of the drug in humans. Pharmacologic information based on in vitro data using human biomaterials or pharmacologic animal models, or relevant details about in vivo study designs or results (e.g., drug interaction studies), may be included in this section if essential to understand dosing or drug interaction information presented in other sections of the labeling. This section must include the following subsections:

(A) 12.1 Mechanism of action. This subsection must summarize what is known about the established mechanism(s) of the drug's action in humans at various levels (e.g., receptor, membrane, tissue, organ, whole body). If the mechanism of action is not known, this subsection must contain a statement about the lack of information.

(B) 12.2 Pharmacodynamics. This subsection must include a description of any biochemical or physiologic pharmacologic effects of the drug or active metabolites related to the drug's clinical effect in preventing, diagnosing, mitigating, curing, or treating disease, or those related to adverse effects or toxicity. Exposure-response relationships (e.g., concentration-response, dose-response) and time course of pharmacodynamic response (including short-term clinical response) must be included if known. If this information is unknown, this subsection must contain a statement about the lack of information. Detailed dosing or monitoring recommendations based on pharmacodynamic information that appear in other sections (e.g., "Warnings and Precautions" or "Dosage and Administration") must not be repeated in this subsection, but the location of such recommendations must be referenced.

(C) 12.3 Pharmacokinetics. This subsection must describe the clinically significant pharmacokinetics of a drug or active metabolites, (i.e., pertinent absorption, distribution, metabolism, and excretion parameters). Information regarding bioavailability, the effect of food, minimum concentration (C_{min}), maximum concentration (C_{max}), time to maximum concentration (T_{max}), area under the curve (AUC), pertinent half-lives ($t_{1/2}$), time to reach steady state, extent of accumulation, route(s) of elimination, clearance (renal, hepatic, total), mechanisms of clearance (e.g., specific enzyme systems), drug/drug and drug/food (e.g., dietary supplements, grapefruit juice) pharmacokinetic interactions (including inhibition, induction, and genetic characteristics), and volume of distribution (V_d) must be presented if clinically significant. Information regarding nonlinearity in pharmacokinetic parameters, changes in pharmacokinetics over time, and binding (plasma protein, erythrocyte) parameters must also be presented if clinically significant. This section must also include the results of pharmacokinetic studies (e.g., of metabolism or interaction) that establish the absence of an effect, including pertinent human studies and in vitro data. Dosing recommendations based on clinically significant factors that change the product's pharmacokinetics (e.g., age, gender, race, hepatic or renal dysfunction, concomitant therapy) that appear in other sections (e.g., "Warnings and Precautions," "Dosage and Administration" or "Use in Specific Populations") must not be repeated in this subsection, but the location of such recommendations must be referenced.

(ii) Data that demonstrate activity or effectiveness in in vitro or animal tests and that have not been shown by adequate and well-controlled clinical studies to be pertinent to clinical use may be included under this section only under the following circumstances:

(A) In vitro data for anti-infective drugs may be included if the data are immediately preceded by the statement "The following in vitro data are available but their clinical significance is unknown."

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(B) For other classes of drugs, in vitro and animal data that have not been shown by adequate and well-controlled studies, as defined in § 314.126(b) of this chapter, to be necessary for the safe and effective use may be included in this section only if a waiver is granted under § 201.58 or § 314.126(c) of this chapter.

(14) 13 Nonclinical toxicology. This section must contain the following subsections as appropriate:

(i) 13.1 Carcinogenesis, mutagenesis, impairment of fertility. This subsection must state whether long term studies in animals have been performed to evaluate carcinogenic potential and, if so, the species and results. If results from reproduction studies or other data in animals raise concern about mutagenesis or impairment of fertility in either males or females, this must be described. Any precautionary statement on these topics must include practical, relevant advice to the prescriber on the significance of these animal findings. Human data suggesting that the drug may be carcinogenic or mutagenic, or suggesting that it impairs fertility, as described in the “Warnings and Precautions” section, must not be included in this subsection of the labeling.

(ii) 13.2 Animal toxicology and/or pharmacology. Significant animal data necessary for safe and effective use of the drug in humans that is not incorporated in other sections of labeling must be included in this section (e.g., specifics about studies used to support approval under § 314.600 or § 601.90 of this chapter, the absence of chronic animal toxicity data for a drug that is administered over prolonged periods or is implanted in the body).

(15) 14 Clinical studies. This section must discuss those clinical studies that facilitate an understanding of how to use the drug safely and effectively. Ordinarily, this section will describe the studies that support effectiveness for the labeled indication(s), including discussion of study design, population, endpoints, and results, but must not include an encyclopedic listing of all, or even most, studies performed as part of the product’s clinical development program. If a specific important clinical study is mentioned in any section of the labeling required under §§ 201.56 and 201.57 because the study is essential to an understandable presentation of the information in that section of the labeling, any detailed discussion of the study must appear in this section.

(i) For drug products other than biological products, any clinical study that is discussed in prescription drug labeling that relates to an indication for or use of the drug must be adequate and well-controlled as described in § 314.126(b) of this chapter and must not imply or suggest indications or uses or dosing regimens not stated in the “Indications and Usage” or “Dosage and Administration” section. For biological products, any clinical study that is discussed that relates to an indication for or use of the biological product must constitute or contribute to substantial evidence and must not imply or suggest indications or uses or dosing regimens not stated in the “Indications and Usage” or “Dosage and Administration” section.

(ii) Any discussion of a clinical study that relates to a risk from the use of the drug must also refer to the other sections of the labeling where the risk is identified or discussed.

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(16) 15 References. When prescription drug labeling must summarize or otherwise rely on a recommendation by an authoritative scientific body, or on a standardized methodology, scale, or technique, because the information is important to prescribing decisions, the labeling may include a reference to the source of the information.

(17) 16 How supplied/storage and handling. This section must contain information on the available dosage forms to which the labeling applies and for which the manufacturer or distributor is responsible. The information must include, as appropriate:

(i) The strength or potency of the dosage form in metric system (e.g., 10 milligram tablets) and, if the apothecary system is used, a statement of the strength in parentheses after the metric designation;

(ii) The units in which the dosage form is ordinarily available for prescribing by practitioners (e.g., bottles of 100);

(iii) Appropriate information to facilitate identification of the dosage forms, such as shape, color, coating, scoring, imprinting, and National Drug Code number; and

(iv) Special handling and storage conditions.

(18) 17 Patient counseling information. This section must contain information necessary for patients to use the drug safely and effectively (e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects). Any FDA-approved patient labeling must be referenced in this section and the full text of such patient labeling must be reprinted immediately following this section or, alternatively, accompany the prescription drug labeling. Any FDA-approved patient labeling printed immediately following this section or accompanying the labeling is subject to the type size requirements in paragraph (d)(6) of this section, except for a Medication Guide to be detached and distributed to patients in compliance with § 208.24 of this chapter. Medication Guides for distribution to patients are subject to the type size requirements set forth in § 208.20 of this chapter.

(d) Format requirements. All labeling information required under paragraphs (a), (b), and (c) of this section must be printed in accordance with the following specifications:

(1) All headings and subheadings required by paragraphs (a) and (c) of this section must be highlighted by bold type that prominently distinguishes the headings and subheadings from other labeling information. Reverse type is not permitted as a form of highlighting.

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- (2) A horizontal line must separate the information required by paragraphs (a), (b), and (c) of this section.
- (3) The headings listed in paragraphs (a)(5) through (a)(13) of this section must be presented in the center of a horizontal line.
- (4) If there are multiple subheadings listed under paragraphs (a)(4) through (a)(13) of this section, each subheading must be preceded by a bullet point.
- (5) The labeling information required by paragraphs (a)(1) through (a)(4), (a)(11)(ii) through (a)(11)(iv), and (a)(14) of this section must be in bold print.
- (6) The letter height or type size for all labeling information, headings, and subheadings set forth in paragraphs (a), (b), and (c) of this section must be a minimum of 8 points, except for labeling information that is on or within the package from which the drug is to be dispensed, which must be a minimum of 6 points.
- (7) The identifying numbers required by § 201.56(d) and paragraphs (c)(1) through (c)(18) of this section must be presented in bold print and must precede the heading or subheading by at least two square em's (i.e., two squares of the size of the letter "m" in 8 point type).
- (8) The information required by paragraph (a) of this section, not including the information required under paragraph (a)(4) of this section, must be limited in length to an amount that, if printed in 2 columns on a standard sized piece of typing paper (8 1/2 by 11 inches), single spaced, in 8 point type with 1/2-inch margins on all sides and between columns, would fit on one-half of the page.
- (9) Sections or subsections of labeling that are identified as containing recent major changes under paragraph (a)(5) of this section must be highlighted in the full prescribing information by the inclusion of a vertical line on the left edge of the new or modified text.
- (10) For the information required by paragraph (b) of this section, each section heading must be in bold print. Each subheading within a section must be indented and not bolded.

Credits

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End of Document

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Code of Federal Regulations**Title 21. Food and Drugs****Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)****Subchapter C. Drugs: General****Part 201. Labeling (Refs & Annos)****Subpart C. Labeling Requirements for over-the-Counter Drugs (Refs & Annos)****21 C.F.R. § 201.80**

§ 201.80 Specific requirements on content and format of labeling for human prescription drug and biological products; older drugs not described in § 201.56(b)(1).

Effective: June 30, 2015

Currentness

Each section heading listed in § 201.56(d), if not omitted under § 201.56(d)(3), shall contain the following information in the following order:

(a) Description.

(1) Under this section heading, the labeling shall contain:

(i) The proprietary name and the established name, if any, as defined in section 502(e)(2) of the act, of the drug;

(ii) The type of dosage form and the route of administration to which the labeling applies;

(iii) The same qualitative and/or quantitative ingredient information as required under § 201.100(b) for labels;

(iv) If the product is sterile, a statement of that fact;

(v) The pharmacological or therapeutic class of the drug;

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(vi) The chemical name and structural formula of the drug;

(vii) If the product is radioactive, a statement of the important nuclear physical characteristics, such as the principal radiation emission data, external radiation, and physical decay characteristics.

(2) If appropriate, other important chemical or physical information, such as physical constants, or pH, shall be stated.

(b) Clinical Pharmacology.

(1) Under this section heading, the labeling shall contain a concise factual summary of the clinical pharmacology and actions of the drug in humans. The summary may include information based on in vitro and/or animal data if the information is essential to a description of the biochemical and/or physiological mode of action of the drug or is otherwise pertinent to human therapeutics. Pharmacokinetic information that is important to safe and effective use of the drug is required, if known, e.g., degree and rate of absorption, pathways of biotransformation, percentage of dose as unchanged drug and metabolites, rate or half-time of elimination, concentration in body fluids associated with therapeutic and/or toxic effects, degree of binding to plasma proteins, degree of uptake by a particular organ or in the fetus, and passage across the blood brain barrier. Inclusion of pharmacokinetic information is restricted to that which relates to clinical use of the drug. If the pharmacological mode of action of the drug is unknown or if important metabolic or pharmacokinetic data in humans are unavailable, the labeling shall contain a statement about the lack of information.

(2) Data that demonstrate activity or effectiveness in in vitro or animal tests and that have not been shown by adequate and well-controlled clinical studies to be pertinent to clinical use may be included under this section of the labeling only under the following circumstances:

(i) In vitro data for anti-infective drugs may be included if the data are immediately preceded by the statement “The following in vitro data are available but their clinical significance is unknown.”

(ii) For other classes of drugs, in vitro and animal data that have not been shown by adequate and well-controlled clinical studies, as defined in § 314.126(b) of this chapter, to be pertinent to clinical use may be used only if a waiver is granted under § 201.58 or § 314.126(c) of this chapter.

(c) Indications and Usage.

(1) Under this section heading, the labeling shall state that:

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(i) The drug is indicated in the treatment, prevention, or diagnosis of a recognized disease or condition, e.g., [penicillin](#) is indicated for the treatment of pneumonia due to susceptible pneumococci; and/or

(ii) The drug is indicated for the treatment, prevention, or diagnosis of an important manifestation of a disease or condition, e.g., [chlorothiazide](#) is indicated for the treatment of edema in patients with congestive heart failure; and/or

(iii) The drug is indicated for the relief of symptoms associated with a disease or syndrome, e.g., [chlorpheniramine](#) is indicated for the symptomatic relief of nasal congestion in patients with vasomotor rhinitis; and/or

(iv) The drug, if used for a particular indication only in conjunction with a primary mode of therapy, e.g., diet, surgery, or some other drug, is an adjunct to the mode of therapy.

(2)(i) For drug products other than biological products, all indications listed in this section must be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in [§ 314.126\(b\)](#) of this chapter unless the requirement is waived under [§ 201.58](#) or [§ 314.126\(c\)](#) of this chapter. Indications or uses must not be implied or suggested in other sections of labeling if not included in this section.

(ii) For biological products, all indications listed in this section must be supported by substantial evidence of effectiveness. Indications or uses must not be implied or suggested in other sections of labeling if not included in this section.

(3) This section of the labeling shall also contain the following additional information:

(i) If evidence is available to support the safety and effectiveness of the drug only in selected subgroups of the larger population with a disease, syndrome, or symptom under consideration, e.g., patients with mild disease or patients in a special age group, the labeling shall describe the available evidence and state the limitations of usefulness of the drug. The labeling shall also identify specific tests needed for selection or monitoring of the patients who need the drug, e.g., microbe susceptibility tests. Information on the approximate kind, degree, and duration of improvement to be anticipated shall be stated if available and shall be based on substantial evidence derived from adequate and well-controlled studies as defined in [§ 314.126\(b\)](#) of this chapter unless the requirement is waived under [§ 201.58](#) or [§ 314.126\(c\)](#) of this chapter. If the information is relevant to the recommended intervals between doses, the usual duration of treatment, or any modification of dosage, it shall be stated in the “Dosage and Administration” section of the labeling and referenced in this section.

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(ii) If safety considerations are such that the drug should be reserved for certain situations, e.g., cases refractory to other drugs, this information shall be stated in this section.

(iii) If there are specific conditions that should be met before the drug is used on a long-term basis, e.g., demonstration of responsiveness to the drug in a short-term trial, the labeling shall identify the conditions; or, if the indications for long-term use are different from those for short-term use, the labeling shall identify the specific indications for each use.

(iv) If there is a common belief that the drug may be effective for a certain use or if there is a common use of the drug for a condition, but the preponderance of evidence related to the use or condition shows that the drug is ineffective, the Food and Drug Administration may require that the labeling state that there is a lack of evidence that the drug is effective for that use or condition.

(v) Any statements comparing the safety or effectiveness, either greater or less, of the drug with other agents for the same indication shall be supported by adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless this requirement is waived under § 201.58 or § 314.126(c) of this chapter.

(d) Contraindications. Under this section heading, the labeling shall describe those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit. These situations include administration of the drug to patients known to have a hypersensitivity to it; use of the drug in patients who, because of their particular age, sex, concomitant therapy, disease state, or other condition, have a substantial risk of being harmed by it; or continued use of the drug in the face of an unacceptably hazardous adverse reaction. Known hazards and not theoretical possibilities shall be listed, e.g., if hypersensitivity to the drug has not been demonstrated, it should not be listed as a contraindication. If no contraindications are known, this section of the labeling shall state “None known.”

(e) Warnings. Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved. A specific warning relating to a use not provided for under the “Indications and Usage” section of the labeling may be required by the Food and Drug Administration if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard. Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. The boxed warning ordinarily shall be based on clinical data, but serious animal toxicity may also be the basis of a boxed warning in the absence of clinical data. If a boxed warning is required, its location will be specified by the Food and Drug Administration. The frequency of these serious adverse reactions and, if known, the approximate mortality and morbidity rates for patients sustaining the reaction, which are important to safe and effective use of the drug, shall be expressed as provided under the “Adverse Reactions” section of the labeling.

(f) Precautions. Under this section heading, the labeling shall contain the following subsections as appropriate for the drug:

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(1) General. This subsection of the labeling shall contain information regarding any special care to be exercised by the practitioner for safe and effective use of the drug, e.g., precautions not required under any other specific section or subsection of the labeling.

(2) Information for patients. This subsection must contain information necessary for patients to use the drug safely and effectively (e.g., precautions concerning driving or the concomitant use of other substances that may have harmful additive effects). Any FDA-approved patient labeling must be referenced in this section and the full text of such patient labeling must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling. The type size requirement for the Medication Guide set forth in § 208.20 of this chapter does not apply to the Medication Guide that is reprinted in or accompanying the prescription drug labeling unless such Medication Guide is to be detached and distributed to patients in compliance with § 208.24 of this chapter.

(3) Laboratory tests. This subsection of the labeling shall identify any laboratory tests that may be helpful in following the patient's response or in identifying possible adverse reactions. If appropriate, information shall be provided on such factors as the range of normal and abnormal values expected in the particular situation and the recommended frequency with which tests should be done before, during, and after therapy.

(4)(i) Drug interactions. This subsection of the labeling shall contain specific practical guidance for the physician on preventing clinically significant drug/drug and drug/food interactions that may occur in vivo in patients taking the drug. Specific drugs or classes of drugs with which the drug to which the labeling applies may interact in vivo shall be identified, and the mechanism(s) of the interaction shall be briefly described. Information in this subsection of the labeling shall be limited to that pertaining to clinical use of the drug in patients. Drug interactions supported only by animal or in vitro experiments may not ordinarily be included, but animal or in vitro data may be used if shown to be clinically relevant. Drug incompatibilities, i.e., drug interactions that may occur when drugs are mixed in vitro, as in a solution for intravenous administration, shall be discussed under the "Dosage and Administration" section of the labeling rather than under this subsection of the labeling.

(ii) Drug/laboratory test interactions. This subsection of the labeling shall contain practical guidance on known interference of the drug with laboratory tests.

(5) Carcinogenesis, mutagenesis, impairment of fertility. This subsection of the labeling shall state whether long-term studies in animals have been performed to evaluate carcinogenic potential and, if so, the species and results. If reproduction studies or other data in animals reveal a problem or potential problem concerning mutagenesis or impairment of fertility in either males or females, the information shall be described. Any precautionary statement on these topics shall include practical, relevant advice to the physician on the significance of these animal findings. If there is evidence from human data that the drug may be carcinogenic or mutagenic or that it impairs fertility, this information shall be included under the "Warnings" section of the labeling. Also, under "Precautions," the labeling shall state: "See 'Warnings' section for information on carcinogenesis, mutagenesis, and impairment of fertility."

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(6) Pregnancy. This subsection of the labeling may be omitted only if the drug is not absorbed systemically and the drug is not known to have a potential for indirect harm to the fetus. For all other drugs, this subsection of the labeling shall contain the following information:

(i) Teratogenic effects. Under this heading the labeling shall identify one of the following categories that applies to the drug, and the labeling shall bear the statement required under the category:

(a) If adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of a risk in later trimesters), the labeling shall state: “Studies in pregnant women have not shown that (name of drug) increases the risk of fetal abnormalities if administered during the first (second, third, or all) trimester(s) of pregnancy. If this drug is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, however, (name of drug) should be used during pregnancy only if clearly needed.” The labeling shall also contain a description of the human studies. If animal reproduction studies are available and they fail to demonstrate a risk to the fetus, the labeling shall also state: “Reproduction studies have been performed in (kinds of animal(s)) at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to (name of drug).” The labeling shall also contain a description of available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(b) If animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women, the labeling shall state: “Reproduction studies have been performed in (kind(s) of animal(s)) at doses up to (x) times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to (name of drug). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.” If animal reproduction studies have shown an adverse effect (other than decrease in fertility), but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus during the first trimester of pregnancy (and there is no evidence of a risk in later trimesters), the labeling shall state: “Reproduction studies in (kind(s) of animal(s)) have shown (describe findings) at (x) times the human dose. Studies in pregnant women, however, have not shown that (name of drug) increases the risk of abnormalities when administered during the first (second, third, or all) trimester(s) of pregnancy. Despite the animal findings, it would appear that the possibility of fetal harm is remote, if the drug is used during pregnancy. Nevertheless, because the studies in humans cannot rule out the possibility of harm, (name of drug) should be used during pregnancy only if clearly needed.” The labeling shall also contain a description of the human studies and a description of available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(c) If animal reproduction studies have shown an adverse effect on the fetus, if there are no adequate and well-controlled studies in humans, and if the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks, the labeling shall state: “(Name of drug) has been shown to be teratogenic (or to have an embryocidal effect or other adverse effect) in (name(s) of species) when given in doses (x) times the human dose. There are no adequate and well-controlled studies in pregnant women. (Name of drug) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.” The labeling shall contain a

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description of the animal studies. If there are no animal reproduction studies and no adequate and well-controlled studies in humans, the labeling shall state: "Animal reproduction studies have not been conducted with (name of drug). It is also not known whether (name of drug) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. (Name of drug) should be given to a pregnant woman only if clearly needed." The labeling shall contain a description of any available data on the effect of the drug on the later growth, development, and functional maturation of the child.

(d) If there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective), the labeling shall state: "See 'Warnings' section." Under the "Warnings" section, the labeling states: "(Name of drug) can cause fetal harm when administered to a pregnant woman. (Describe the human data and any pertinent animal data.) If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus."

(e) If studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available), the labeling shall state: "See 'Contraindications' section." Under "Contraindications," the labeling shall state: "(Name of drug) may (can) cause fetal harm when administered to a pregnant woman. (Describe the human data and any pertinent animal data.) (Name of drug) is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus."

(ii) Nonteratogenic effects. Under this heading the labeling shall contain other information on the drug's effects on reproduction and the drug's use during pregnancy that is not required specifically by one of the pregnancy categories, if the information is relevant to the safe and effective use of the drug. Information required under this heading shall include nonteratogenic effects in the fetus or newborn infant (for example, withdrawal symptoms or hypoglycemia) that may occur because of a pregnant woman's chronic use of the drug for a preexisting condition or disease.

(7) Labor and delivery. If the drug has a recognized use during labor or delivery (vaginal or abdominal delivery), whether or not the use is stated in the indications section of the labeling, this subsection of the labeling shall describe the available information about the effect of the drug on the mother and the fetus, on the duration of labor or delivery, on the possibility that forceps delivery or other intervention or resuscitation of the newborn will be necessary, and the effect of the drug on the later growth, development, and functional maturation of the child. If any information required under this subsection is unknown, this subsection of the labeling shall state that the information is unknown.

(8) Nursing mothers.

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(i) If a drug is absorbed systemically, this subsection of the labeling shall contain, if known, information about excretion of the drug in human milk and effects on the nursing infant. Pertinent adverse effects observed in animal offspring shall be described.

(ii) If a drug is absorbed systemically and is known to be excreted in human milk, this subsection of the labeling shall contain one of the following statements, as appropriate. If the drug is associated with serious adverse reactions or if the drug has a known tumorigenic potential, the labeling shall state: "Because of the potential for serious adverse reactions in nursing infants from (name of drug)(or, "Because of the potential for tumorigenicity shown for (name of drug) in (animal or human) studies), a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother." If the drug is not associated with serious adverse reactions and does not have a known tumorigenic potential, the labeling shall state: "Caution should be exercised when (name of drug) is administered to a nursing woman."

(iii) If a drug is absorbed systemically and information on excretion in human milk is unknown, this subsection of the labeling shall contain one of the following statements, as appropriate. If the drug is associated with serious adverse reactions or has a known tumorigenic potential, the labeling shall state: "It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from (name of drug)(or, "Because of the potential for tumorigenicity shown for (name of drug) in (animal or human) studies), a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother." If the drug is not associated with serious adverse reactions and does not have a known tumorigenic potential, the labeling shall state: "It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when (name of drug) is administered to a nursing woman."

(9) Pediatric use.

(i) Pediatric population(s)/pediatric patient(s): For the purposes of paragraphs (f)(9)(ii) through (f)(9)(viii) of this section, the terms pediatric population(s) and pediatric patient(s) are defined as the pediatric age group, from birth to 16 years, including age groups often called neonates, infants, children, and adolescents.

(ii) If there is a specific pediatric indication (i.e., an indication different from those approved for adults) that is supported by adequate and well-controlled studies in the pediatric population, it shall be described under the "Indications and Usage" section of the labeling, and appropriate pediatric dosage information shall be given under the "Dosage and Administration" section of the labeling. The "Pediatric use" subsection shall cite any limitations on the pediatric indication, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. Data summarized in this subsection of the labeling should be discussed in more detail, if appropriate, under the "Clinical Pharmacology" or "Clinical Studies" section. As appropriate, this information shall also be contained in the "Contraindications," "Warnings," and elsewhere in the "Precautions" sections.

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(iii) If there are specific statements on pediatric use of the drug for an indication also approved for adults that are based on adequate and well-controlled studies in the pediatric population, they shall be summarized in the “Pediatric use” subsection of the labeling and discussed in more detail, if appropriate, under the “Clinical Pharmacology” and “Clinical Studies” sections. Appropriate pediatric dosage shall be given under the “Dosage and Administration” section of the labeling. The “Pediatric use” subsection of the labeling shall also cite any limitations on the pediatric use statement, need for specific monitoring, specific hazards associated with use of the drug in any subsets of the pediatric population (e.g., neonates), differences between pediatric and adult responses to the drug, and other information related to the safe and effective pediatric use of the drug. As appropriate, this information shall also be contained in the “Contraindications,” “Warnings,” and elsewhere in the “Precautions” sections.

(iv) FDA may approve a drug for pediatric use based on adequate and well-controlled studies in adults, with other information supporting pediatric use. In such cases, the agency will have concluded that the course of the disease and the effects of the drug, both beneficial and adverse, are sufficiently similar in the pediatric and adult populations to permit extrapolation from the adult efficacy data to pediatric patients. The additional information supporting pediatric use must ordinarily include data on the pharmacokinetics of the drug in the pediatric population for determination of appropriate dosage. Other information, such as data from pharmacodynamic studies of the drug in the pediatric population, data from other studies supporting the safety or effectiveness of the drug in pediatric patients, pertinent premarketing or postmarketing studies or experience, may be necessary to show that the drug can be used safely and effectively in pediatric patients. When a drug is approved for pediatric use based on adequate and well-controlled studies in adults with other information supporting pediatric use, the “Pediatric use” subsection of the labeling shall contain either the following statement, or a reasonable alternative: “The safety and effectiveness of (drug name) have been established in the age groups ____ to ____ (note any limitations, e.g., no data for pediatric patients under 2, or only applicable to certain indications approved in adults). Use of (drug name) in these age groups is supported by evidence from adequate and well-controlled studies of (drug name) in adults with additional data (insert wording that accurately describes the data submitted to support a finding of substantial evidence of effectiveness in the pediatric population).” Data summarized in the preceding prescribed statement in this subsection of the labeling shall be discussed in more detail, if appropriate, under the “Clinical Pharmacology” or the “Clinical Studies” section. For example, pediatric pharmacokinetic or pharmacodynamic studies and dose-response information should be described in the “Clinical Pharmacology” section. Pediatric dosing instructions shall be included in the “Dosage and Administration” section of the labeling. Any differences between pediatric and adult responses, need for specific monitoring, dosing adjustments, and any other information related to safe and effective use of the drug in pediatric patients shall be cited briefly in the “Pediatric use” subsection and, as appropriate, in the “Contraindications,” “Warnings,” “Precautions,” and “Dosage and Administration” sections.

(v) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for a particular pediatric population, the “Pediatric use” subsection of the labeling shall contain an appropriate statement such as “Safety and effectiveness in pediatric patients below the age of (____) have not been established.” If use of the drug in this pediatric population is associated with a specific hazard, the hazard shall be described in this subsection of the labeling, or, if appropriate, the hazard shall be stated in the “Contraindications” or “Warnings” section of the labeling and this subsection shall refer to it.

(vi) If the requirements for a finding of substantial evidence to support a pediatric indication or a pediatric use statement have not been met for any pediatric population, this subsection of the labeling shall contain the following statement: “Safety and effectiveness in pediatric patients have not been established.” If use of the drug in premature or neonatal infants, or other pediatric subgroups, is associated with a specific hazard, the hazard shall be described in this subsection of the labeling, or, if appropriate, the hazard shall be stated in the “Contraindications” or “Warnings” section of the

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labeling and this subsection shall refer to it.

(vii) If the sponsor believes that none of the statements described in paragraphs (f)(9)(ii) through (f)(9)(vi) of this section is appropriate or relevant to the labeling of a particular drug, the sponsor shall provide reasons for omission of the statements and may propose alternative statement(s). FDA may permit use of an alternative statement if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug's labeling and that the alternative statement is accurate and appropriate.

(viii) If the drug product contains one or more inactive ingredients that present an increased risk of toxic effects to neonates or other pediatric subgroups, a special note of this risk shall be made, generally in the "Contraindications," "Warnings," or "Precautions" section.

(10) Geriatric use.

(i) A specific geriatric indication, if any, that is supported by adequate and well-controlled studies in the geriatric population shall be described under the "Indications and Usage" section of the labeling, and appropriate geriatric dosage shall be stated under the "Dosage and Administration" section of the labeling. The "Geriatric use" subsection shall cite any limitations on the geriatric indication, need for specific monitoring, specific hazards associated with the geriatric indication, and other information related to the safe and effective use of the drug in the geriatric population. Unless otherwise noted, information contained in the "Geriatric use" subsection of the labeling shall pertain to use of the drug in persons 65 years of age and older. Data summarized in this subsection of the labeling shall be discussed in more detail, if appropriate, under "Clinical Pharmacology" or the "Clinical Studies" section. As appropriate, this information shall also be contained in "Contraindications," "Warnings," and elsewhere in "Precautions."

(ii) Specific statements on geriatric use of the drug for an indication approved for adults generally, as distinguished from a specific geriatric indication, shall be contained in the "Geriatric use" subsection and shall reflect all information available to the sponsor that is relevant to the appropriate use of the drug in elderly patients. This information includes detailed results from controlled studies that are available to the sponsor and pertinent information from well-documented studies obtained from a literature search. Controlled studies include those that are part of the marketing application and other relevant studies available to the sponsor that have not been previously submitted in the investigational new drug application, new drug application, biological license application, or a supplement or amendment to one of these applications (e.g., postmarketing studies or adverse drug reaction reports). The "Geriatric use" subsection shall contain the following statement(s) or reasonable alternative, as applicable, taking into account available information:

(A) If clinical studies did not include sufficient numbers of subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects, and other reported clinical experience has not identified such differences, the "Geriatric use" subsection shall include the following statement:

"Clinical studies of (name of drug) did not include sufficient numbers of subjects aged 65 and over to determine

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whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.”

(B) If clinical studies (including studies that are part of marketing applications and other relevant studies available to the sponsor that have not been submitted in the sponsor’s applications) included enough elderly subjects to make it likely that differences in safety or effectiveness between elderly and younger subjects would have been detected, but no such differences (in safety or effectiveness) were observed, and other reported clinical experience has not identified such differences, the “Geriatric use” subsection shall contain the following statement:

Of the total number of subjects in clinical studies of (name of drug), ___ percent were 65 and over, while ___ percent were 75 and over. (Alternatively, the labeling may state the total number of subjects included in the studies who were 65 and over and 75 and over.) No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

(C) If evidence from clinical studies and other reported clinical experience available to the sponsor indicates that use of the drug in elderly patients is associated with differences in safety or effectiveness, or requires specific monitoring or dosage adjustment, the “Geriatric use” subsection of the labeling shall contain a brief description of observed differences or specific monitoring or dosage requirements and, as appropriate, shall refer to more detailed discussions in the “Contraindications,” “Warnings,” “Dosage and Administration,” or other sections of the labeling.

(iii)(A) If specific pharmacokinetic or pharmacodynamic studies have been carried out in the elderly, they shall be described briefly in the “Geriatric use” subsection of the labeling and in detail under the “Clinical Pharmacology” section. The “Clinical Pharmacology” section and “Drug interactions” subsection of the “Precautions” section ordinarily contain information on drug-disease and drug-drug interactions that is particularly relevant to the elderly, who are more likely to have concomitant illness and to utilize concomitant drugs.

(B) If a drug is known to be substantially excreted by the kidney, the “Geriatric use” subsection shall include the statement:

“This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.”

(iv) If use of the drug in the elderly appears to cause a specific hazard, the hazard shall be described in the “Geriatric use” subsection of the labeling, or, if appropriate, the hazard shall be stated in the “Contraindications,” “Warnings,” or

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“Precautions” section of the labeling, and the “Geriatric use” subsection shall refer to those sections.

(v) Labeling under paragraphs (f)(10)(i) through (f)(10)(iii) of this section may include statements, if they would be useful in enhancing safe use of the drug, that reflect good clinical practice or past experience in a particular situation, e.g., for a sedating drug, it could be stated that:

“Sedating drugs may cause confusion and over-sedation in the elderly; elderly patients generally should be started on low doses of (name of drug) and observed closely.”

(vi) If the sponsor believes that none of the requirements described in paragraphs (f)(10)(i) through (f)(10)(v) of this section is appropriate or relevant to the labeling of a particular drug, the sponsor shall provide reasons for omission of the statements and may propose an alternative statement. FDA may permit omission of the statements if FDA determines that no statement described in those paragraphs is appropriate or relevant to the drug’s labeling. FDA may permit use of an alternative statement if the agency determines that such statement is accurate and appropriate.

(g) Adverse Reactions. An adverse reaction is an undesirable effect, reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence.

(1) This section of the labeling shall list the adverse reactions that occur with the drug and with drugs in the same pharmacologically active and chemically related class, if applicable.

(2) In this listing, adverse reactions may be categorized by organ system, by severity of the reaction, by frequency, or by toxicological mechanism, or by a combination of these, as appropriate. If frequency information from adequate clinical studies is available, the categories and the adverse reactions within each category shall be listed in decreasing order of frequency. An adverse reaction that is significantly more severe than the other reactions listed in a category, however, shall be listed before those reactions, regardless of its frequency. If frequency information from adequate clinical studies is not available, the categories and adverse reactions within each category shall be listed in decreasing order of severity. The approximate frequency of each adverse reaction shall be expressed in rough estimates or orders of magnitude essentially as follows: “The most frequent adverse reaction(s) to (name of drug) is (are)(list reactions). This (these) occur(s) in about (e.g., one-third of patients; one in 30 patients; less than one-tenth of patients). Less frequent adverse reactions are (list reactions), which occur in approximately (e.g., one in 100 patients). Other adverse reactions, which occur rarely, in approximately (e.g., one in 1,000 patients), are (list reactions).” Percent figures may not ordinarily be used unless they are documented by adequate and well-controlled studies as defined in § 314.126(b) of this chapter, they are shown to reflect general experience, and they do not falsely imply a greater degree of accuracy than actually exists.

(3) The “Warnings” section of the labeling or, if appropriate, the “Contraindications” section of the labeling shall identify any potentially fatal adverse reaction.

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(4) Any claim comparing the drug to which the labeling applies with other drugs in terms of frequency, severity, or character of adverse reactions shall be based on adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless this requirement is waived under § 201.58 or § 314.126(c) of this chapter.

(h) Drug Abuse and Dependence. Under this section heading, the labeling shall contain the following subsections, as appropriate for the drug:

(1) Controlled Substance. If the drug is controlled by the Drug Enforcement Administration, the schedule in which it is controlled shall be stated.

(2) Abuse. This subsection of the labeling shall be based primarily on human data and human experience, but pertinent animal data may also be used. This subsection shall state the types of abuse that can occur with the drug and the adverse reactions pertinent to them. Particularly susceptible patient populations shall be identified.

(3) Dependence. This subsection of the labeling shall describe characteristic effects resulting from both psychological and physical dependence that occur with the drug and shall identify the quantity of the drug over a period of time that may lead to tolerance or dependence, or both. Details shall be provided on the adverse effects of chronic abuse and the effects of abrupt withdrawal. Procedures necessary to diagnose the dependent state shall be provided, and the principles of treating the effects of abrupt withdrawal shall be described.

(i) Overdosage. Under this section heading, the labeling shall describe the signs, symptoms, and laboratory findings of acute overdosage and the general principles of treatment. This section shall be based on human data, when available. If human data are unavailable, appropriate animal and in vitro data may be used. Specific information shall be provided about the following:

(1) Signs, symptoms, and laboratory findings associated with an overdosage of the drug.

(2) Complications that can occur with the drug (for example, organ toxicity or delayed acidosis).

(3) Oral LD₅₀ of the drug in animals; concentrations of the drug in biologic fluids associated with toxicity and/or death; physiologic variables influencing excretion of the drug, such as urine pH; and factors that influence the dose response relationship of the drug, such as tolerance. The pharmacokinetic data given in the "Clinical Pharmacology" section also may be referenced here, if applicable to overdoses.

(4) The amount of the drug in a single dose that is ordinarily associated with symptoms of overdosage and the amount of the drug in a single dose that is likely to be life-threatening.

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(5) Whether the drug is dialyzable.

(6) Recommended general treatment procedures and specific measures for support of vital functions, such as proven antidotes, gastric lavage, and forced diuresis. Unqualified recommendations for which data are lacking with the specific drug or class of drugs, especially treatment using another drug (for example, central nervous system stimulants, respiratory stimulants) may not be stated unless specific data or scientific rationale exists to support safe and effective use.

(j) Dosage and Administration. This section of the labeling shall state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established; dosages shall be stated for each indication when appropriate. Dosing regimens must not be implied or suggested in other sections of labeling if not included in this section. This section shall also state the intervals recommended between doses, the optimal method of titrating dosage, the usual duration of treatment, and any modification of dosage needed in special patient populations, e.g., in children, in geriatric age groups, or in patients with renal or hepatic disease. Specific tables or monographs may be included to clarify dosage schedules. Radiation dosimetry information shall be stated for both the patient receiving a radioactive drug and the person administering it. This section shall also contain specific direction on dilution, preparation (including the strength of the final dosage solution, when prepared according to instructions, in terms of milligrams active ingredient per milliliter of reconstituted solution, unless another measure of the strength is more appropriate), and administration of the dosage form, if needed, e.g., the rate of administration of parenteral drug in milligrams per minute; storage conditions for stability of the drug or reconstituted drug, when important; essential information on drug incompatibilities if the drug is mixed in vitro with other drugs; and the following statement for parenterals: "Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit."

(k) How Supplied. This section of the labeling shall contain information on the available dosage forms to which the labeling applies and for which the manufacturer or distributor is responsible. The information shall ordinarily include:

(1) The strength of the dosage form, e.g., 10-milligram tablets, in metric system and, if the apothecary system is used, a statement of the strength is placed in parentheses after the metric designation;

(2) The units in which the dosage form is ordinarily available for prescribing by practitioners, e.g., bottles of 100;

(3) Appropriate information to facilitate identification of the dosage forms, such as shape, color, coating, scoring, and National Drug Code; and

(4) Special handling and storage conditions.

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(l) Animal Pharmacology and/or Animal Toxicology. In most cases, the labeling need not include this section. Significant animal data necessary for safe and effective use of the drug in humans shall ordinarily be included in one or more of the other sections of the labeling, as appropriate. Commonly for a drug that has been marketed for a long time, and in rare cases for a new drug, chronic animal toxicity studies have not been performed or completed for a drug that is administered over prolonged periods or is implanted in the body. The unavailability of such data shall be stated in the appropriate section of the labeling for the drug. If the pertinent animal data cannot be appropriately incorporated into other sections of the labeling, this section may be used.

(m) “Clinical Studies” and “References”. These sections may appear in labeling in the place of a detailed discussion of a subject that is of limited interest but nonetheless important. A reference to a specific important clinical study may be made in any section of the format required under §§ 201.56 and 201.57 if the study is essential to an understandable presentation of the available information. References may appear in sections of the labeling format, other than the “Clinical Studies” or “References” section, in rare circumstances only. A clinical study or reference may be cited in prescription drug labeling only under the following conditions:

(1)(i) If the clinical study is cited in the labeling in place of a detailed discussion of data and information concerning an indication for use of the drug, the clinical study must constitute an adequate and well-controlled study as described in § 314.126(b) of this chapter, except for biological products, and must not imply or suggest indications or uses or dosing regimens not stated in the “Indications and Usage” or “Dosage and Administration” section.

(ii) When prescription drug labeling must summarize or otherwise rely on a recommendation by an authoritative scientific body, or on a standardized methodology, scale, or technique, because the information is important to prescribing decisions, the labeling may include a reference to the source of the information.

(2) If the clinical study or reference is cited in the labeling in the place of a detailed discussion of data and information concerning a risk or risks from the use of the drug, the risk or risks shall also be identified or discussed in the appropriate section of the labeling for the drug.

Credits

[44 FR 37462, June 26, 1979; 55 FR 11576, March 29, 1990; 59 FR 64249, Dec. 13, 1994; 62 FR 45325, Aug. 27, 1997; 63 FR 66396, Dec. 1, 1998. Redesignated and amended at 71 FR 3988, 3996, Jan. 24, 2006; 79 FR 72103, Dec. 4, 2014]

SOURCE: 40 FR 13998, March 27, 1975; 41 FR 6908, Feb. 13, 1976; 51 FR 8182, March 7, 1986; 51 FR 43904, Dec. 5, 1986; 52 FR 2111, Jan. 20, 1987; 53 FR 4135, Feb. 12, 1988; 54 FR 39635, Sept. 27, 1989; 57 FR 54300, Nov. 18, 1992; 58 FR 45201, Aug. 26, 1993; 62 FR 51515, Oct. 1, 1997; 63 FR 26698, May 13, 1998; 64 FR 400, Jan. 5, 1999, unless otherwise noted.

ADD225

§ 201.80 Specific requirements on content and format of..., 21 C.F.R. § 201.80

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

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§ 1301.71 Security requirements generally., 21 C.F.R. § 1301.71

Code of Federal Regulations

Title 21. Food and Drugs

Chapter II. Drug Enforcement Administration, Department of Justice

Part 1301. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (Refs & Annos)

Security Requirements

21 C.F.R. § 1301.71

§ 1301.71 Security requirements generally.

Effective: October 9, 2014

Currentness

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in §§ 1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in §§ 1301.72–1301.76 may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:

- (1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);
- (2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);
- (3) The quantity of controlled substances handled;
- (4) The location of the premises and the relationship such location bears on security needs;

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- (5) The type of building construction comprising the facility and the general characteristics of the building or buildings;
- (6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;
- (7) The type of closures on vaults, safes, and secure enclosures;
- (8) The adequacy of key control systems and/or combination lock control systems;
- (9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;
- (10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
- (11) The adequacy of supervision over employees having access to manufacturing and storage areas;
- (12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
- (13) The availability of local police protection or of the registrant's or applicant's security personnel;
- (14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; and
- (15) The applicability of the security requirements contained in all Federal, State, and local laws and regulations governing the management of waste.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a noncontrolled substance being listed on any schedule, or as a result of a significant increase in the

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quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in §§ 1301.72–1301.76 when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in §§ 1301.72–1301.76 may submit any plans, blueprints, sketches or other materials regarding the proposed security system either to the Special Agent in Charge in the region in which the system will be used, or to the Regulatory Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(e) Physical security controls of locations registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 on April 30, 1971, shall be deemed to comply substantially with the standards set forth in §§ 1301.72, 1301.73 and 1301.75. Any new facilities or work or storage areas constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Administration, shall not necessarily be deemed to comply substantially with the standards set forth in §§ 1301.72, 1301.73 and 1301.75, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Administration.

(f) A collector shall not employ, as an agent or employee who has access to or influence over controlled substances acquired by collection, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause. For purposes of this subsection, “for cause” means in lieu of, or as a consequence of, any Federal or State administrative, civil, or criminal action resulting from an investigation of the individual’s handling of controlled substances.

Credits

[36 FR 18729, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 47 FR 41735, Sept. 22, 1982; 51 FR 5319, Feb. 13, 1986; 68 FR 41228, July 11, 2003; 70 FR 22595, May 2, 2005; 75 FR 10677, March 9, 2010; 79 FR 53561, Sept. 9, 2014]

SOURCE: 36 FR 7778, April 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973; 50 FR 31589, Aug. 5, 1985; 69 FR 55347, Sept. 14, 2004; 71 FR 51112, Aug. 29, 2006; 74 FR 15621, April 6, 2009; 79 FR 53560, Sept. 9, 2014, unless otherwise noted.

AUTHORITY: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957, 958, 965.

Current through Sept. 24, 2015; 80 FR 57688.

ADD229

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§ 1301.72 Physical security controls for non-practitioners;..., 21 C.F.R. § 1301.72

Code of Federal Regulations**Title 21. Food and Drugs****Chapter II. Drug Enforcement Administration, Department of Justice****Part 1301. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (Refs & Annos)****Security Requirements****21 C.F.R. § 1301.72**

§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

Effective: October 9, 2014

[Currentness](#)

(a) Schedules I and II. Raw material, bulk materials awaiting further processing, finished products which are controlled substances listed in Schedule I or II (except GHB that is manufactured or distributed in accordance with an exemption under section 505(i) of the Federal Food Drug and Cosmetic Act which shall be subject to the requirements of paragraph (b) of this section), and sealed mail-back packages and inner liners acquired in accordance with part 1317 of this chapter, shall be stored in one of the following secured areas:

(1) Where small quantities permit, a safe or steel cabinet;

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

(2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a

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steel door, combination or key lock, and an alarm system; or

(3) A vault constructed after September 1, 1971:

(i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with ½ -inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

(ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(iii) Which vault, if operations require it to remain open for frequent access, is equipped with a “day-gate” which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) The door of which vault is equipped with contact switches; and

(vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.

(b) Schedules III, IV and V. Raw material, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V, and GHB when it is manufactured or distributed in accordance with an exemption under section 505(i) of the FFDCA, shall be stored in the following secure storage areas:

(1) A safe or steel cabinet as described in paragraph (a)(1) of this section;

(2) A vault as described in paragraph (a)(2) or (3) of this section equipped with an alarm system as described in

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paragraph (b)(4)(v) of this section;

(3) A building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications:

(i) Has an electronic alarm system as described in paragraph (b)(4)(v) of this section,

(ii) Is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:

(a) In the case of key locks, shall require key control which limits access to a limited number of employees, or;

(b) In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination;

(4) A cage, located within a building on the premises, meeting the following specifications:

(i) Having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:

(a) At least one inch in diameter;

(b) Set in concrete or installed with lag bolts that are pinned or brazed; and

(c) Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches;

(ii) Having a mesh construction with openings of not more than two and one-half inches across the square,

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(iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height,

(iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b)(3)(ii), and

(v) Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Administrator may approve;

(5) An enclosure of masonry or other material, approved in writing by the Administrator as providing security comparable to a cage;

(6) A building or enclosure within a building which has been inspected and approved by DEA or its predecessor agency, BND, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated;

(7) Such other secure storage areas as may be approved by the Administrator after considering the factors listed in § 1301.71(b);

(8)(i) Schedule III through V controlled substances may be stored with Schedules I and II controlled substances under security measures provided by 21 CFR 1301.72(a);

(ii) Non-controlled drugs, substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by 21 CFR 1301.72(b), provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the Special Agent in Charge of DEA for the area in which such storage area is situated. Any such permission tendered must be upon the Special Agent in Charge's written determination that such non-segregated storage does not diminish security effectiveness for Schedules III through V controlled substances.

(c) Multiple storage areas. Where several types or classes of controlled substances are handled separately by the registrant or

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applicant for different purposes (e.g., returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(d) Accessibility to storage areas. The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

Credits

[[36 FR 18730](#), Sept. 21, 1971, as amended at [37 FR 15919](#), Aug. 8, 1972. Redesignated at [38 FR 26609](#), Sept. 24, 1973; [47 FR 41735](#), Sept. 22, 1982; [62 FR 13957](#), March 24, 1997; [65 FR 13238](#), March 13, 2000; [68 FR 41228](#), July 11, 2003; [70 FR 22595](#), May 2, 2005; [79 FR 53562](#), Sept. 9, 2014]

SOURCE: [36 FR 7778](#), April 24, 1971. Redesignated at [38 FR 26609](#), Sept. 24, 1973; [50 FR 31589](#), Aug. 5, 1985; [69 FR 55347](#), Sept. 14, 2004; [71 FR 51112](#), Aug. 29, 2006; [74 FR 15621](#), April 6, 2009; [79 FR 53560](#), Sept. 9, 2014, unless otherwise noted.

AUTHORITY: [21 U.S.C. 821, 822, 823, 824, 831, 871\(b\), 875, 877, 886a, 951, 952, 953, 956, 957, 958, 965](#).

Current through Sept. 24, 2015; [80 FR 57688](#).

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§ 1301.74 Other security controls for non-practitioners; narcotic..., 21 C.F.R. § 1301.74

Code of Federal Regulations**Title 21. Food and Drugs****Chapter II. Drug Enforcement Administration, Department of Justice****Part 1301. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (Refs & Annos)****Security Requirements****21 C.F.R. § 1301.74**

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs.

Effective: October 9, 2014

[Currentness](#)

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. The supplier is responsible for reporting all in-transit losses of controlled substances by the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the theft or loss. Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;

(2) The specific controlled substances lost;

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(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of part 1305 of the chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term “customer” includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in § 1301.72. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

(g) Before the initial distribution of carfentanil etorphine hydrochloride and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substances(s) by contacting the Drug Enforcement Administration.

(h) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed

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practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

(i) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either (1) the licensed practitioner, (2) a registered nurse under the direction of the licensed practitioner, (3) a licensed practical nurse under the direction of the licensed practitioner, or (4) a pharmacist under the direction of the licensed practitioner.

(j) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

(l) DEA may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

(m) A reverse distributor shall not employ, as an agent or employee who has access to or influence over controlled substances, any person who has been convicted of any felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause. For purposes of this subsection, “for cause” means in lieu of, or as a consequence of, any Federal or State administrative, civil, or criminal action resulting from an investigation of the individual’s handling of controlled substances.

Credits

[[36 FR 7778](#), Apr. 24, 1971; [36 FR 13386](#), July 21, 1971, as amended at [36 FR 18731](#), Sept. 21, 1971; [38 FR 26609](#) Sept. 24, 1973; [54 FR 33674](#), Aug. 16, 1989; [70 FR 47096](#), Aug. 12, 2005; [79 FR 53562](#), Sept. 9, 2014]

SOURCE: [36 FR 7778](#), April 24, 1971. Redesignated at [38 FR 26609](#), Sept. 24, 1973; [50 FR 31589](#), Aug. 5, 1985; [69 FR 55347](#), Sept. 14, 2004; [71 FR 51112](#), Aug. 29, 2006; [74 FR 15621](#), April 6, 2009; [79 FR 53560](#), Sept. 9, 2014, unless otherwise noted.

ADD238

§ 1301.74 Other security controls for non-practitioners; narcotic..., 21 C.F.R. § 1301.74

AUTHORITY: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957, 958, 965.

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§ 1301.75 Physical security controls for practitioners., 21 C.F.R. § 1301.75

Code of Federal Regulations**Title 21. Food and Drugs****Chapter II. Drug Enforcement Administration, Department of Justice****Part 1301. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances (Refs & Annos)****Security Requirements****21 C.F.R. § 1301.75****§ 1301.75 Physical security controls for practitioners.****Effective: October 9, 2014**

Currentness

- (a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.
- (b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.
- (c) Sealed mail-back packages and inner liners collected in accordance with part 1317 of this chapter shall only be stored at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access, except as authorized by [§ 1317.80\(d\)](#).
- (d) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration.
- (e) Carfentanil etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.

Credits

[[39 FR 3674](#), Jan. 29, 1974, as amended at [39 FR 17838](#), May 21, 1974; [54 FR 33674](#), Aug. 16, 1989; [62 FR 13957](#), March 24, 1997; [79 FR 53562](#), Sept. 9, 2014]

ADD240

§ 1301.75 Physical security controls for practitioners., 21 C.F.R. § 1301.75

SOURCE: [36 FR 7778](#), April 24, 1971. Redesignated at [38 FR 26609](#), Sept. 24, 1973; [50 FR 31589](#), Aug. 5, 1985; [69 FR 55347](#), Sept. 14, 2004; [71 FR 51112](#), Aug. 29, 2006; [74 FR 15621](#), April 6, 2009; [79 FR 53560](#), Sept. 9, 2014, unless otherwise noted.

AUTHORITY: [21 U.S.C. 821, 822, 823, 824, 831, 871\(b\), 875, 877, 886a, 951, 952, 953, 956, 957, 958, 965](#).

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§ 1304.22 Records for manufacturers, distributors, dispensers,..., 21 C.F.R. § 1304.22

Code of Federal Regulations**Title 21. Food and Drugs****Chapter II. Drug Enforcement Administration, Department of Justice****Part 1304. Records and Reports of Registrants (Refs & Annos)****Continuing Records****21 C.F.R. § 1304.22**

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, exporters, registrants that reverse distribute, and collectors.

Effective: October 9, 2014

Currentness

Each person registered or authorized (by §§ 1301.13(e), 1307.11, 1307.13, or part 1317 of this chapter) to manufacture, distribute, dispense, import, export, reverse distribute, destroy, conduct research with controlled substances, or collect controlled substances from ultimate users, shall maintain records with the information listed in paragraphs (a) through (f) of this section.

(a) Records for manufacturers. Each person registered or authorized to manufacture controlled substances shall maintain records with the following information:

(1) For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,

(i) The name of the substance;

(ii) The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

(iii) The quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;

(iv) The quantity imported directly by the registrant (under a registration as an importer) for use in manufacture by him/her, including the date, quantity, and import permit or declaration number for each importation;

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(v) The quantity used to manufacture the same substance in finished form, including:

(A) The date and batch or other identifying number of each manufacture;

(B) The quantity used in the manufacture;

(C) The finished form (e.g., 10–milligram tablets or 10–milligram concentration per fluid ounce or milliliter);

(D) The number of units of finished form manufactured;

(E) The quantity used in quality control;

(F) The quantity lost during manufacturing and the causes therefore, if known;

(G) The total quantity of the substance contained in the finished form;

(H) The theoretical and actual yields; and

(I) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(vi) The quantity used to manufacture other controlled and noncontrolled substances, including the name of each substance manufactured and the information required in paragraph (a)(1)(v) of this section;

(vii) The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;

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(viii) The quantity exported directly by the registrant (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;

(ix) The quantity distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed; and

(x) The originals of all written certifications of available procurement quotas submitted by other persons (as required by § 1303.12(f) of this chapter) relating to each order requiring the distribution of a basic class of controlled substance listed in Schedule I or II.

(2) For each controlled substance in finished form,

(i) The name of the substance;

(ii) Each finished form (e.g., 10–milligram tablet or 10–milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100–tablet bottle or 3–milliliter vial);

(iii) The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to paragraph (a)(1)(v) of this section;

(iv) The number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from whom the units were acquired;

(v) The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;

(vi) The number of units and/or commercial containers manufactured by the registrant from units in finished form received from others or imported, including:

(A) The date and batch or other identifying number of each manufacture;

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(B) The operation performed (e.g., repackaging or relabeling);

(C) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes for such losses, if known; and

(D) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

(vii) The number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed;

(viii) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and

(ix) The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

(b) Records for distributors. Except as provided in paragraph (e) of this section, each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (v), (vii), (viii) and (ix) of this section.

(c) Records for dispensers and researchers. Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to the requirements of this paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription must also comply with [§ 1304.26](#).

(d) Records for importers and exporters. Each person registered or authorized to import or export controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2) (i), (iv), (v) and (vii) of

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this section. In addition, the quantity disposed of in any other manner by the registrant (except quantities used in manufacturing by an importer under a registration as a manufacturer), which quantities are to be recorded pursuant to paragraphs (a)(1) (iv) and (v) of this section; and the quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume), and the export permit or declaration number for each exportation, but excluding all quantities (and number of units and volumes) manufactured by an exporter under a registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to paragraphs (a)(1)(xiii) or (a)(2)(xiii) of this section.

(e) Records for registrants that reverse distribute. Each person registered or authorized to reverse distribute controlled substances shall maintain records with the following information for each controlled substance:

(1) For controlled substances acquired for the purpose of return or recall to the manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf pursuant to part 1317 of this chapter:

(i) The date of receipt; the name and quantity of each controlled substance received; the name, address, and registration number of the person from whom the substance was received; and the reason for return (e.g., recall or return); and

(ii) The date of return to the manufacturer or other registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; the name and quantity of each controlled substance returned; the name, address, and registration number of the person from whom the substance was received; the name, address, and registration number of the registrant to whom the substance was returned; and the method of return (e.g., common or contract carrier).

(2) For controlled substances acquired from registrant inventory for destruction pursuant to § 1317.05(a)(2), (b)(2), and (b)(4) of this chapter:

(i) The date of receipt; the name and quantity of each controlled substance received; and the name, address, and registration number of the person from whom the substance was received; and

(ii) The date, place, and method of destruction; the name and quantity of each controlled substance destroyed; the name, address, and registration number of the person from whom the substance was received; and the name and signatures of the two employees of the registrant that witnessed the destruction.

(3) The total quantity of each controlled substance shall be recorded in accordance with the following:

(i) For controlled substances in bulk form: To the nearest metric unit weight or volume consistent with unit size;

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(ii) For controlled substances in finished form: Each finished form (e.g., 10–milligram tablet or 10–milligram concentration per fluid ounce or milliliter); the number of units or volume of finished form in each commercial container (e.g., 100–tablet bottle or 3–milliliter vial); and the number of commercial containers of each such finished form (e.g., four 100–tablet bottles or six 3–milliliter vials); and

(iii) For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: If the substance is listed in Schedule I or II make an exact count or measure of the contents; or if the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made.

(4) For each sealed inner liner acquired from collectors or law enforcement and each sealed mail-back package acquired from law enforcement pursuant to [§ 1317.55](#) of this chapter:

(i) The number of sealed inner liners acquired from other persons, including the date of acquisition, the number and, for sealed inner liners the size (e.g., five 10–gallon liners, etc.), of all sealed inner liners and mail-back packages acquired to inventory, the unique identification number of each sealed inner liner and mail-back package, and the name, address, and, for registrants, the registration number of the person from whom the sealed inner liners and mail-back packages were received, and

(ii) The date, place, and method of destruction; the number of sealed inner liners and mail-back packages destroyed; the name, address, and, for registrants, the registration number of the person from whom the sealed inner liners and mail-back packages were received; the number and, for sealed inner liners the size (e.g., five 10–gallon liners, etc.), of all sealed inner liners and mail-back packages destroyed; the unique identification number of each sealed inner liner and sealed mail-back package destroyed; and the name and signatures of the two employees of the registrant that witnessed the destruction.

(5) For all records, the record of receipt shall be maintained together with the corresponding record of return or destruction (DEA Form 41).

(f) Records for collectors. Each person registered or authorized to collect controlled substances from ultimate users shall maintain the following records:

(1) Mail–Back Packages:

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(i) For unused packages that the collector makes available to ultimate users and other authorized non-registrants at the collector's registered address: The date made available, the number of packages, and the unique identification number of each package;

(ii) For unused packages provided to a third party to make available to ultimate users and other authorized non-registrants: The name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification numbers;

(iii) For sealed mail-back packages received by the collector: Date of receipt and the unique identification number on the individual package; and

(iv) For sealed mail-back packages destroyed on-site by the collector: Number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witnessed the destruction.

(2) Collection receptacle inner liners:

(i) Date each unused inner liner acquired, unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each unused inner liner acquired;

(ii) Date each inner liner is installed, the address of the location where each inner liner is installed, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each installed inner liner, the registration number of the collector, and the names and signatures of the two employees that witnessed each installation;

(iii) Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each inner liner removed, the registration number of the collector, and the names and signatures of the two employees that witnessed each removal;

(iv) Date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage;

(v) Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the unique identification number and the size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner transferred, and the names and signatures of the two

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employees that transferred each sealed inner liner to the reverse distributor or distributor; and

(vi) For sealed inner liners destroyed on-site by the collector: The same information required of reverse distributors in paragraph (e)(4)(ii) of this section.

Credits

[[36 FR 7792](#), April 24, 1971, as amended at [36 FR 13386](#), July 21, 1971; [36 FR 18732](#), Sept. 21, 1971; [37 FR 15920](#), Aug. 8, 1972. Redesignated at [38 FR 26609](#), Sept. 24, 1973; [62 FR 13960](#), March 24, 1997; [68 FR 41229](#), July 11, 2003; [70 FR 293](#), Jan. 4, 2005; [70 FR 22595](#), May 2, 2005; [79 FR 53563](#), Sept. 9, 2014]

SOURCE: [50 FR 40523](#), Oct. 4, 1985; [62 FR 13958](#), March 24, 1997; [74 FR 15623](#), April 6, 2009; [79 FR 53562](#), Sept. 9, 2014, unless otherwise noted.

AUTHORITY: [21 U.S.C. 821](#), [827](#), [831](#), [871\(b\)](#), [958\(e\)-\(g\)](#), and [965](#), unless otherwise noted.

Current through Sept. 24, 2015; 80 FR 57688.

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§ 1306.04 Purpose of issue of prescription., 21 C.F.R. § 1306.04

Code of Federal Regulations**Title 21. Food and Drugs****Chapter II. Drug Enforcement Administration, Department of Justice****Part 1306. Prescriptions (Refs & Annos)****General Information****21 C.F.R. § 1306.04****§ 1306.04 Purpose of issue of prescription.****Effective: July 25, 2005**

Currentness

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act ([21 U.S.C. 829](#)) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for “detoxification treatment” or “maintenance treatment,” unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in [§ 1301.28](#) of this chapter.

Credits

[[36 FR 7799](#), Apr. 24, 1971. Redesignated at [38 FR 26609](#), Sept. 24, 1973, and amended at [39 FR 37986](#), Oct. 25, 1974; [70 FR 36343](#), June 23, 2005]

SOURCE: [[36 FR 7799](#), April 24, 1971; [36 FR 13386](#), July 21, 1971; Redesignated at [38 FR 26609](#), Sept. 24, 1973; [51 FR 5316](#), Feb. 13, 1986; [74 FR 15624](#), April 6, 2009, unless otherwise noted], unless otherwise noted.

AUTHORITY: [21 U.S.C. 821, 829, 831, 871\(b\)](#), unless otherwise noted.

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§ 1306.04 Purpose of issue of prescription., 21 C.F.R. § 1306.04

Current through Sept. 24, 2015; 80 FR 57688.

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ADD251§ 4000. Short title, CA BUS & PROF § 4000

[West's Annotated California Codes](#)[Business and Professions Code \(Refs & Annos\)](#)[Division 2. Healing Arts \(Refs & Annos\)](#)[Chapter 9. Pharmacy \(Refs & Annos\)](#)[Article 1. Administration \(Refs & Annos\)](#)

West's Ann.Cal.Bus. & Prof.Code § 4000

§ 4000. Short title

Currentness

This chapter constitutes, and may be cited as, the Pharmacy Law.

Credits

(Added by Stats.1996, c. 890 (A.B.2802), § 3.)

West's Ann. Cal. Bus. & Prof. Code § 4000, CA BUS & PROF § 4000

Current with urgency legislation through Ch. 351 of 2015 Reg.Sess.

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ADD252

§ 109910. “Department” defined, CA HLTH & S § 109910

West’s Annotated California Codes

Health and Safety Code (Refs & Annos)

Division 104. Environmental Health (Refs & Annos)

Part 5. Sherman Food, Drug, and Cosmetic Laws (Refs & Annos)

Chapter 1. General Provisions and Definitions (Refs & Annos)

West’s Ann.Cal.Health & Safety Code § 109910

§ 109910. “Department” defined

Currentness

“Department” means the State Department of Health Services.

Credits

(Added by Stats.1995, c. 415 (S.B.1360), § 6.)

West’s Ann. Cal. Health & Safety Code § 109910, CA HLTH & S § 109910

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ADD253

§ 110045. Administration and enforcement, CA HLTH & S § 110045

West's Annotated California Codes

Health and Safety Code (Refs & Annos)

Division 104. Environmental Health (Refs & Annos)

Part 5. Sherman Food, Drug, and Cosmetic Laws (Refs & Annos)

Chapter 2. Administration (Refs & Annos)

Article 1. General (Refs & Annos)

West's Ann.Cal.Health & Safety Code § 110045

§ 110045. Administration and enforcement

Currentness

The department shall administer and enforce this part.

Credits

(Added by Stats.1995, c. 415 (S.B.1360), § 6.)

West's Ann. Cal. Health & Safety Code § 110045, CA HLTH & S § 110045

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